



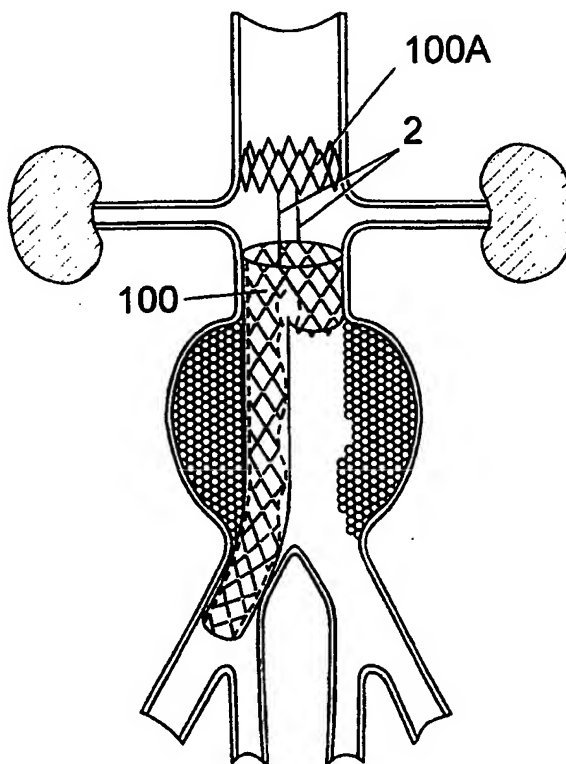
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(54) Title: ENDOVASCULAR PROSTHESES, AN INTRODUCER AND SURGICAL PACKAGE THEREFOR AND HAEMOSTATIC VALVE

(57) Abstract

There is provided an endovascular prosthesis suitable for an aortic aneurysm, especially in the renal aorta. The prosthesis includes a separate anchor stent separated from the main stent by at least one linking strut or wire. Usually 2, 3 or 4 linking struts or wires will be present. The stents are desirably formed from a shape memory alloy such as nitinol. The main stent may be covered with a suitable fabric or membrane, but the anchor stent is preferably unclad. An introducer, with a facility to deploy the anchor stent after correct positioning of the main stent, is also described. A haemostatic valve comprising an elastomeric sleeve, which is preferably pinched off by rotation of one end, is further described.



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1 "Endovascular Prostheses, an introducer and surgical
2 package therefor and haemostatic valve"

3

4 This invention relates to endovascular protheses, and
5 relates more particularly but not exclusively to stents
6 for aortic aneurysms in humans and other mammals.

7

8 It has been proposed that an aneurysm in the aorta
9 should be treated by insertion therein of an
10 endovascular stent covered by a sheath of fabric which
11 is substantially impermeable to blood. The stent is
12 introduced into the artery in a radially collapsed
13 state, displaced to overlap the aneurysm, and then
14 allowed to expand radially such that it self-anchors on
15 the arterial wall on either side of the aneurysm. This
16 decreases the pressure on the weakened walls of the
17 aneurysm, preventing further weakening thereof and
18 decreasing the possibility of rupture. Although better
19 anchorage of the stent could be obtained by anchoring
20 the upper end of the stent in the aorta above the renal
21 arteries, the fabric covering of the stent would block
22 renal blood flow, with unacceptable consequences for
23 the health of the patient. However, omitting the
24 fabric from a supra-renally anchored stent allows the
25 anchoring stent to be placed above the renal arteries

1 while maintaining renal perfusion.

2

3 According to a first aspect of the present invention
4 there is provided an endovascular prosthesis for a
5 vascular aneurysm, the prosthesis comprising a tubular
6 membrane means which is substantially impermeable to
7 blood and which is disposable to convey blood between
8 substantially non-aneurysmal regions on either side of
9 the aneurysm, the prosthesis further comprising
10 selectively deployable anchor means for anchoring in
11 the vascular wall at an anchoring location displaced
12 from the aneurysm, the anchor means being linked to the
13 tubular membrane means by link means comprised in the
14 prosthesis, the link means being such as to cause
15 minimal turbulence in side-branching blood vessels
16 branching from a point between the aneurysm and the
17 anchoring location.

18

19 The anchor means preferably comprises an expandable
20 metal mesh annular stent which is preferably unclad by
21 any membrane or fabric.

22

23 The link means preferably comprises at least one
24 longitudinally extending strut or wire. Preferably the
25 link means comprises 2, 3 or 4 separate struts or wires
26 which may be spaced equidistantly.

27

28 The tubular membrane means preferably comprises a
29 sleeve of a fabric which is preferably a fabric as
30 described in an International Patent Application
31 No PCT/GB97/02071 located over an expandable metal mesh
32 tubular stent which is in a radially collapsed form for
33 emplacement of the prosthesis and which is expandable
34 when located to shunt the aneurysm.

35

36 The stents comprised in the anchor means and in the

1 tubular membrane means are preferably formed of a shape
2 memory alloy which may be an alloy comprising nickel
3 and titanium, for example nitinol.

4
5 According to a second aspect of the present invention
6 there is provided an introducer for endovascular
7 emplacement of an endovascular prosthesis according to
8 the first aspect of the present invention, the
9 introducer comprising a flexible tubular guide means
10 externally dimensioned for passage along a vascular
11 duct from an extracorporeal location to the site of the
12 aneurysm and to the anchoring location, the guide means
13 being internally dimensioned to encompass the
14 prosthesis in its initially radially collapsed state
15 without preventing controlled longitudinal displacement
16 of the prosthesis relative to the guide means during
17 emplacement of the prosthesis, the introducer further
18 comprising a hollow capsule for containing the anchor
19 means in an initially radially collapsed state, one end
20 of the capsule being detached from the remainder of the
21 capsule and inserted inside the remainder of the
22 capsule to lie within or adjacent the other end of the
23 capsule such as to leave the remainder of the capsule
24 between said inserted one end and the other end of the
25 capsule for containing the collapsed anchor means, the
26 introducer additionally comprising displacement control
27 means for longitudinally displacing the capsule with
28 respect to the tubular guide means, the introducer
29 further comprising capsule end replacement means for
30 replacing said one end of the capsule following
31 deployment of the anchor means whereby to facilitate
32 withdrawal of the capsule following emplacement of the
33 prosthesis.

34
35 The capsule end replacement means may comprise spring
36 means disposed within the capsule between the opposite

1 ends thereof to urge the detached end of the capsule
2 towards its replaced position. Alternatively, the
3 capsule end replacement means may comprise Bowden cable
4 means having a core wire threaded through the
5 longitudinal axis of the introducer as a guide wire for
6 the introducer, and having a Bowden sheath coupled to
7 the detached end of the capsule, the Bowden sheath
8 preferably functioning as the displacement control
9 means.

10

11 According to a third aspect of the present invention,
12 there is provided a surgical package comprising the
13 operative combination of an endovascular prosthesis
14 according to the first aspect of the present invention
15 and an introducer according to the second aspect of the
16 present invention, the tubular membrane means of the
17 prosthesis being in an initially radially collapsed
18 configuration and located within the tubular guide
19 means, the anchor means of the prosthesis being in an
20 initially radially collapsed configuration and located
21 with the capsule, the anchor means being linked to the
22 tubular membrane means by the link means such that the
23 anchor-encompassing capsule is also linked to the
24 tubular membrane means, the capsule being disposed at
25 the leading end of the tubular guide means, the
26 displacement control means being threaded through the
27 tubular guide means and through the tubular membrane
28 means.

29

30 The displacement control means preferably extends
31 through the end of the tubular guide means remote from
32 the end of the guide means initially holding the
33 prosthesis for extracorporeal control of the
34 displacement of the capsule.

35

36 According to a fourth aspect of the present invention

1 there is provided a haemostatic valve, optionally for
2 use with the surgical package according to the third
3 aspect of the present invention, the haemostatic valve
4 comprising an elastomeric sleeve, a first end of the
5 sleeve being sealed to a first sealing means, a second
6 end of the sleeve being sealed to a second sealing
7 means, and pinch control means for controllably
8 pinching the sleeve where it extends between the two
9 sealing means whereby controllably to seal around the
10 tubular guide means or the displacement control means
11 as it passes through the sleeve. One side of the valve
12 will be sealed to the introducer in a blood tight
13 manner. Optionally, the valve may comprise a coupling
14 means to allow connection and disconnection to the
15 introducer.

16
17 The pinch control means may comprise pressurisation
18 means for externally pressurising the sleeve means to
19 pinch the sleeve onto whichever article is currently
20 extending through the sleeve. Alternatively, the pinch
21 control means may comprise rotation control means for
22 controllably inducing relative rotation of the first
23 and second sealing means about a common axis such as to
24 twist the sleeve about its longitudinal axis where it
25 extends between the two sealing means whereby to
26 collapse the sleeve onto whichever article is currently
27 extending through the sleeve. The rotation control
28 means preferably comprises bearing means rotationally
29 coupling the two sealing means for relative rotation
30 about a common axis, spring means acting between the
31 two sealing means to bias them into relative rotation
32 in a sense tending to induce rotational collapse of the
33 sleeve, and manually engageable means attached to or
34 forming part of the sealing means by which the bias of
35 the spring means may be controllably counteracted by
36 the application of manual force such as controllably to

1 open the valve by a selected amount.

2

3 The present invention further provides a stent formed
4 from a mesh characterised in that said mesh comprises a
5 linking element wherein each end of said element is
6 connected at a connecting point to the mesh and wherein
7 the length of said element exceeds the distance between
8 the connecting points. In one embodiment the linking
9 element comprises an "S"-shaped bend and optionally the
10 linking element itself may be substantially in the form
11 of an "S"-shape. It is an important part of the
12 present invention that at least one linking element has
13 a length that exceeds the distance between its ends
14 when the stent is in its expanded form.

15

16 The linking element permits improved radial and
17 longitudinal flexibility of the mesh, whilst
18 simultaneously retaining a good degree of structural
19 integrity throughout the whole stent.

20

21 In one embodiment the mesh is formed from rows of
22 diamond-like elements arranged longitudinally and
23 linked together by connecting elements, at least one of
24 which (preferably all of which) is a linking elements
25 as defined above, for example comprises an "S"-shaped
26 bend therein. Optionally, some of the points
27 connecting two neighbouring diamonds in each element
28 are absent to provide further flexibility within the
29 mesh. An example is shown in Figure 38A.

30

31 In an alternative embodiment linking elements as
32 defined above alternate with a straight section to form
33 a zig-zag element. Preferably a number of such zig-zag
34 elements are present in the stent and are arranged
35 longitudinally. Each zig-zag element may be off-set
36 relative to its neighbouring zig-zag elements and may

1 be joined thereto by a connecting element, which may
2 itself be diagonally disposed and off-set from the apex
3 of each zig-zag element. Examples are shown in Figures
4 36A and 37A.

5

6 The mesh stent described above may be produced by
7 etching a metal sheet or tube. Desirably the stent is
8 formed from shape memory material, for example nitinol.

9

10 Preferably the endovascular prosthesis described above
11 comprises a stent of the form referred to here, for
12 example having an "S"-shaped linking element. Most
13 preferably the endovascular prosthesis comprises a
14 stent having the mesh pattern shown in one of Figures
15 36 and 38.

16

17 Embodiments of the invention will now be described by
18 way of example, with reference to the accompanying
19 drawings wherein:

20

21 Fig. 1 is a plan view of basic elements of the
22 metal mesh employed in the prosthesis of the
23 invention;

24 Fig. 2 is a plan view of one side of one element
25 of the mesh of Fig. 1 showing the dimensions in
26 millimetres;

27 Figs. 3, 4 and 5 are plan views of alternative
28 forms of the basic elements of the metal mesh;

29 Fig. 6 is a plan view of the development of a
30 preferred form of membrane-expanding stent
31 employed in the prosthesis of the invention;

32 Fig. 7 is a plan view of the development of a
33 contralateral stent;

34 Figs. 8A-8D show various details of a stent having
35 provision for adjustment of its length;

36 Figs. 9A, 9B and 9C are cross-sectional views

1 during and after the deployment of an anchor
2 employed in the prosthesis of the invention;
3 Figs. 10-17 are semi-schematic sections through
4 vascular anatomy, showing the successive stages in
5 the emplacement of a prosthesis in accordance with
6 the invention, by use of an introducer also in
7 accordance with the invention;
8 Figs. 18A and 18B schematically depict one form of
9 haemostatic valve in accordance with the
10 invention;
11 Figs. 19A and 19B schematically depict another
12 form of haemostatic valve in accordance with the
13 invention;
14 Figs. 20 and 21 respectively depict a longitudinal
15 elevation and an end view of a version of the
16 valve of Fig. 19 modified for manual operation,
17 with the valve being fully closed;
18 Figs. 22 and 23 respectively correspond to Figs.
19 20 and 21, but with the valve being partially
20 opened; and
21 Figs. 24-35 show successive stages in the
22 deployment of a prosthesis by means of an
23 introducer in conjunction with a valve, all in
24 accordance with the invention.
25 Figs. 36 shows a mesh pattern suitable for a stent
26 of the present invention where the stent is shown
27 an expanded form in A; the same stent is shown in
28 an unexpanded form in B; and an enlarged view of
29 the circled area of B is shown in C.
30 Fig. 37 shows an alternative mesh pattern suitable
31 for a stent of the present invention wherein the
32 stent is shown in A in an expanded form; the same
33 stent is shown in unexpanded form in B; and an
34 enlarged view of a portion of B is shown in C.
35 Fig. 38 shows an alternative mesh pattern suitable
36 for a stent of present invention wherein the stent is

1 shown in A in an unexpanded form; the same stent
2 is shown in unexpanded form in B.

3

4 For convenience, the mesh pattern of Figs. 36 to
5 38 is depicted in the form of a flat sheet. The
6 mesh itself may either be produced from a sheet
7 (which is welded) or a tube.

8

9 The endovascular prosthesis of the present invention
10 incorporates a full-length stent which is fully
11 articulated or partly articulated. The stent is of
12 mesh form fabricated from a shape memory alloy, and
13 makes use of the super-elastic properties of such
14 alloys. The shape memory alloy may be a binary alloy
15 such as a nickel/titanium alloy, or the alloy may be a
16 tertiary alloy offering improved performance. The
17 stent is covered with a sleeve of biocompatible fabric
18 as a blood-tight membrane, the fabric preferably being
19 as described in WO-A-98/05271.

20

21 The stent mesh is manufactured by cutting or etching
22 memory alloy initially in the form of flat sheet or
23 tube, allowing use of a range of mesh sizes and style
24 of mesh patterns in stent production. Alternatively,
25 the stent mesh may be of wire.

26

27 A basic stent mesh pattern is shown in Fig. 1, wherein
28 the indicated linear dimensions are in millimetres.
29 The diamond pattern of Fig. 1 is formed of a rhomboidal
30 grid of elements (1) as shown in detail in Fig. 2
31 (wherein dimensions are in millimetres). The Fig. 2
32 stent mesh elements (1) are so shaped and dimensioned
33 in order to minimise strain and stress levels as the
34 mesh expands from its fully closed form to its fully
35 open form, with a concomitant increase in the length of
36 the short diagonal of the mesh unit (the horizontal

1 node separation as shown in Fig. 1) from 3mm to 8.43mm.

2

3 It is to be particularly noted that each mesh joint as
4 shown in Fig. 1 is a tri-nodal joint, such that by
5 extending the horizontal and/or vertical legs between
6 the diagonal elements, the mesh dimensions can be
7 selectively altered without affecting the basic
8 geometry. Fig. 3 (which is essentially the same as
9 Fig. 1) shows the basic definitions of the "x"
10 dimension (horizontal) and the "y" dimension
11 (vertical), while Fig. 4 shows an extension of the "x"
12 dimension of the horizontal node link, and Fig. 5 shows
13 an extension of the "y" dimension of the vertical node
14 link. Mesh patterns as depicted in Figs. 4 and 5 are
15 also suitable for use in the present invention.

16

17 Such design flexibility in respect of mesh dimensions
18 allows the creation of a stent mesh pattern which
19 incorporates segments of various lengths, diameters,
20 articulation, or function as may be required.

21

22 Once a particular mesh pattern is selected, for
23 fabrication from a flat sheet the initially flat mesh
24 may be rolled up into a generally tubular shape which
25 can then be secured by mutually welding the now-
26 adjacent points which were initially on opposite edges.
27 Alternatively, the mesh pattern can be produced by
28 etching a tube of shape memory material or by arranging
29 and welding wire into the form required.

30

31 The mesh pattern for a bifurcated aneurysm repair stent
32 100 is shown in Fig. 6 in flat form (ie before being
33 rolled up into a generally tubular shape or as would be
34 achieved by selection cutting and a tubular member
35 formed from a single piece of material). Where the
36 stent is formed from wire, it is possible for a flat

1 sheet of the type shown in Fig. 6 to be formed and
2 then welded, but more generally the stent will be
3 produced in tubular form and in such an embodiment the
4 Fig. 6 shows the mesh pattern in the continuous
5 circumference of the stent (at least for segments A, C
6 and F). The bifurcated stent 100 is in a number of
7 functionally different segments which are individually
8 denoted in Fig. 6 by respective letters A to F. The
9 functions of these segments are as follows:-

10

11 **SEGMENT**

12

13 **A Supra Renal Aortic Anchor**

14 This is a single diamond mesh designed to anchor
15 into the aorta above the renal arteries and will
16 remain uncovered of fabric to allow for
17 incorporation into the vessel wall. Its fully
18 expanded diameter will be the same or greater than
19 the internal diameter of the vessel.

20

21 **B Hanger Links from Supra Renal (A) to Infra Renal**
22 **Segments**

23 These links (2), which are designed to sit
24 dorsoventrally, will allow the stented graft (100)
25 to be positioned just below the renal arteries
26 while the system remains anchored by the supra
27 renal segment (A).

28

29 **C Aortic Sealing Segment**

30 This segment makes use of the basic mesh pattern
31 (see Fig. 1) to create a full diameter stented
32 graft that will sit just below the renal arteries
33 and seal well against the vessel wall.

34

35 **D Bifurcation Segment**

36 At this segment the full diameter Aortic Stent

1 tapers down to form the bifurcation for the graft
2 with one leg truncated (3) and the other leg (5)
3 continuing (E). The truncated leg (3) may have a
4 reverse taper at the tips to aid location and
5 sealing of the independent contralateral leg
6 (110).
7

8 **E Articulated Leg (5)**

9 This segment consists of a mesh pattern where a
10 series of the leg sections have been omitted (4)
11 in order to give the stented graft some degree of
12 flexibility and allow it to accommodate a tortuous
13 vessel while maintaining both some axial rigidity
14 and radial strength. This mesh may form a
15 complete circumference of the graft leg of a
16 diameter that is independent of the diameter of
17 the Aortic Stent segment diameter or it may only
18 form a partial circumference thus increasing
19 flexibility.
20

21 **F Full Iliac Stent**

22 This segment makes use of a basic mesh pattern to
23 create a full circumference stent of a diameter
24 independent of the diameter of the Aortic Stent
25 segment.
26

27 Alternative mesh patterns (see Figs. 36 to 38) may be
28 used in a bifurcated stent of the form shown in Fig. 6.
29

30 The bifurcated stent 100 has one integral full-length
31 leg, the articulated leg 5 (see Figs. 13-17) and merely
32 a socket 6 formed from the short leg 3 for the
33 contralateral leg 110. A suitable mesh pattern for the
34 contralateral leg 110 is shown in Fig. 7, where a basic
35 mesh has a series of connecting sections omitted in
36 order to give some degree of flexibility and yet still

1 retain some axial rigidity and radial strength.
2 Details of the variants of the basic pattern are shown
3 in the fragmentary views of Figs. 7A, 7B and 7C, while
4 details of the weld tab (for securing the mesh in its
5 eventual tubular form) are shown in the fragmentary
6 view of Fig. 7D.
7 Fig. 7A shows the base of a diamond shaped section
8 where a connecting section has been omitted.
9
10 Fig. 7B shows basic sections of two adjacent diamond
11 shaped sections which are not joined together.
12
13 Fig. 7C shows an apex of a diamond shaped section,
14 wherein the apex diamond shaped section is not attached
15 to another diamond shaped section.
16
17 Figs. 8A-8D show a bifurcated stent 120 which is a
18 modification of the stent 100 of Fig. 6. The
19 modification of the stent 120 consists of a secondary
20 stent 122 located in the main leg 5 of the stent 120.
21 By attaching the trailing edge 8 of the fabric sleeve 9
22 to the secondary stent 122, the secondary stent 122 and
23 fabric sleeve 9 can be selectively pulled down (eg from
24 the Fig. 8A configuration to the Fig. 8B configuration)
25 to increase the effective length of the stent 120 from
26 L1 to L2 prior to deployment of the secondary stent 122
27 (Figs. 8C and 8D).
28
29 Upon elongation of the secondary stent 122 any
30 unrequired portion 9A (see Fig. 8C) of sleeve 9 will
31 protrude into the central lumen of the prosthesis and
32 may interfere with the blood flow through the vessel
33 possibly even inducing blood clotting on the surface of
34 the material. This may be prevented by use of a
35 suitably positioned third stent 123 thus preventing the
36 portion of spare material 9A from interfering with the

1 blood flow (see Fig. 8D). The third stent 123
2 effectively clamps the spare material 9A against the
3 leg 5 of the primary stent 100 and against the
4 secondary stent 122.

5
6 Fig. 9A shows, in semi-schematic form, a longitudinal
7 section of a hollow capsule 130 for retaining and
8 eventually selectively deploying the anchor segment 'A'
9 of the stent 100 (Fig. 6). The distal end 132 of the
10 capsule 130 is mounted on a flexible control member
11 320, and the other end 136 of the capsule 130 is
12 detached and temporarily held within the capsule body
13 138. The detached end 136 is urged outwardly by a
14 compression spring 140 self-retained on the control
15 member 320 between the ends 132 and 136; however, the
16 detached end 136 is temporarily held back by the
17 presence inside the capsule body 138 of the radially
18 compressed anchor stent 100A. The partial deployment
19 of the anchor 100A is shown in Fig. 9B, and will be
20 more fully detailed with reference to Fig. 14. At the
21 completion of anchor deployment (Figs. 9C and 15), the
22 detached end 136 is spring biased back to its end-
23 capping position on the body 138 where it facilitates
24 withdrawal of the capsule 130 (downwards as shown in
25 Figs. 9C and 16) while avoiding the trauma that would
26 otherwise be induced by the open end of the capsule
27 body 138. The fully deployed anchor stent 100A is not
28 shown in Fig. 9C.

29
30 Figs. 10-17 show (in semi-schematic and fragmentary
31 form) the sequence of steps involved in the emplacement
32 of the Fig. 6 stent 100 (in tubular form and radially
33 collapsed inside a sleeve of biocompatible fabric) into
34 an aortic system 200 such that the stent 100 and its
35 fabric sleeve 9 will eventually shunt an infra-renal
36 aneurysm 210 but without blocking or inducing

1 unacceptable turbulence in the side-branching renal
2 arteries 220, even though taking advantage of the
3 superior supra-renal anchoring site 230. The stent 100
4 and its sleeve 9 are initially radially collapsed and
5 the stent 100 is located inside a guide tube 300
6 immediately behind the capsule 130 holding the
7 similarly collapsed anchor stent. The guide tube 300
8 is capped by a dilator 310, and the assembly is fed
9 along a guide wire 134 previously inserted into the
10 aortic system 200 (Fig. 10). The dilator 310 (Fig. 10)
11 is removed (Fig. 11), and the capsule 130 extended from
12 the distal end of the guide tube 300, but the anchor
13 stent 100A (Fig. 15) is not yet extended. Utilising X-
14 rays or other monitoring means, the fabric-covered
15 portion of the stent 100 is suitably located to span
16 across the aneurysm 210 (Fig. 12) and its deployment is
17 started by controlled withdrawal of the guide tube 300,
18 such withdrawal continuing until the stent 100 (other
19 than its anchor segment 100A) is fully emplaced so as
20 to span the aneurysm (Fig. 13).

21
22 Final adjustments in the position of the main stent 100
23 are made while such adjustments are relatively easy
24 prior to anchor deployment, and then the control member
25 320 is gently advanced into the patient's body so as to
26 push the capsule 130 upwards (Fig. 14). As the capsule
27 130 advances, the anchor segment 100A is held back by
28 the hanger links 2 (or 100B) (Fig. 6) attached to the
29 lightly self-anchored main part 100C of the stent 100,
30 resulting in the anchor stent 100A being pulled out of
31 the capsule 130 (Figs. 9B and 14), and eventually in
32 complete freeing of the anchor stent 100A (Fig. 15)
33 which anchors in the supra-renal aortic wall 230. The
34 capsule 130 closes itself (Figs. 9C and 16) and is
35 withdrawn (Fig. 17) by removal of the guide wire 134.
36

1 The anchor stent 100A firmly anchors in the supra-renal
2 wall, and thereby firmly anchors the remainder of the
3 prosthesis 100 in an aneurysm-spanning position through
4 the intermediary of the hanger links 2 (or 100B). By
5 suitably positioning the links 2 (or 100B) with respect
6 to the remainder of the stent 100, it is readily
7 arranged such that neither of the links 2 (or 100B)
8 crosses the renal arteries 220, so that despite taking
9 advantage of supra-renal anchoring, the prosthesis 100
10 causes negligible disturbance to renal blood flow. By
11 having the anchor stent 100A uncovered by fabric 9, the
12 bare metal mesh of which the anchor stent 100A is
13 formed readily imbeds in the vascular wall and becomes
14 incorporated into its structure.

15
16 The guide tube 300 of the introducer enters the
17 patient's body through an incision extending into a
18 suitable blood vessel. Excessive loss of blood through
19 the lumens of the prosthesis will result unless
20 precautions are taken to seal the area, but it must
21 still be necessary to extend and retract the necessary
22 parts of the introducer with reasonable facility.
23 Accordingly, a haemostatic valve is a desirable adjunct
24 to the present invention of the prosthesis and its
25 introducer.

26
27 One suitable form of haemostatic valve 400 is shown in
28 longitudinal cross-section in Fig. 18A. The valve 400
29 comprises an annular housing 410 having within it a
30 silicone rubber sleeve 420 retained within the opposite
31 ends of the housing 410 by means of outwardly-acting
32 clamp rings 430. The space between the inside of the
33 housing 410 and the outside of the sleeve 420 (between
34 its opposite ends) is selectively pressurisable via an
35 inflation port 440 formed in the housing 410.

36

1 As shown in Fig. 18A, there is no pressurisation, the
2 sleeve 420 is released and the valve 400 is fully
3 opened. As shown in Fig. 18B, pressurisation is
4 applied via the inflation port 440, which collapses the
5 sleeve 420 to pinch it shut, either onto itself as
6 shown or onto a guide tube or the like (not shown in
7 Figs. 18A or 18B) passing through the valve 400. By
8 sealing one end of the valve 400 to the outer surface
9 of the inducer (either directly or through the
10 intermediary of an adaptor (not shown)), the valve 400
11 can be kept pressurised to prevent blood loss, and
12 depressurised only when (and only to the extent
13 required) to pass a tube or instrument through the
14 sleeve 420.

15

16 Another suitable form of haemostatic valve 500 is shown
17 in longitudinal cross-section in Fig. 19A. As with the
18 valve 400, the valve 500 has an annular housing 510. A
19 control ring 520 is rotatably mounted on the right-hand
20 end of the housing 510. A silicone rubber sleeve 530
21 is located inside the housing 510, with its left end
22 secured to the housing 510 by a clamping ring 540, and
23 its right end secured to the control ring 520 by a
24 further clamping ring 550.

25

26 As shown in Fig. 19A, the control ring 520 is in a
27 rotational position in which the sleeve 530 is
28 untwisted and fully open. By turning the control ring
29 520 relative to the housing 510, the sleeve 530 is
30 twisted and eventually (with sufficient control ring
31 rotation) collapses on itself as shown in Fig. 19B,
32 thereby to pinch off blood flow through the valve 500.

33

34 Figs. 20-23 show a haemostatic valve 600 which is a
35 modified form of the valve 500 (Figs. 19A and 19B)
36 adapted for manual operation and to be spring-biased

- 1 closed. The components of the valve 600 are as
2 follows:-
3
4 601 Adaptor for an Introducer tube. (Different sizes
5 of tube can be fitted to different adaptors);
6 602 O-Ring-seals between rear face of adaptor and
7 front face of rotating finger grip;
8 603 Outer body of valve - incorporates fixed finger
9 grip;
10 604 Rotating finger grip - pushing this against fixed
11 grip helps to untwist the silicone tubing 606
12 against the spring torque and open central hole
13 610. This makes insertion of dilators and graft
14 cartridges much easier;
15 605 Spring - Torsion spring keeps silicone tubing
16 twisted shut like an iris, and keeps rotating
17 finger grip 604 fully open;
18 606 Silicone rubber tube - twisted through 250 degrees
19 maximum. Closing finger grips 604 together
20 reduces twist to 160 degrees, partially opening
21 the central hole 610;
22 607 Fixed sleeve anchor for silicone tube 606 - this
23 provides a location for the torsion spring 605 and
24 an anchor and seal for the tube 606;
25 608 Inner sleeves (at each end of silicone tube 606) -
26 these trap and bond the silicone tube 606 into
27 their anchor sleeves; and
28 609 Bayonet socket for fitting Dilators and graft
29 cartridges.
30 610 Central aperture of the haemostatic valve 600
31 which can be opened and closed to allow items to
32 be admitted or withdrawn from the patient with the
33 minimum blood loss.
34
35 Figs. 20 and 21 show the valve 600 closed under the
36 biasing influence of the spring 605 which twists the

1 silicone rubber tube or sleeve 606 shut (as in the
2 valve 500 of Figs. 19A and 19B). By manually pinching
3 the finger grips 603 and 604 together, as shown in
4 Figs. 22 and 23, the sleeve 606 is untwisted
5 sufficiently to admit the dilator 310 of the introducer
6 without undue resistance, but without undue clearance
7 that would allow excessive leakage of blood from the
8 patient. The central opening 610 can be opened and
9 closed as required to facilitate the insertion and/or
10 removal from the patient of the introducer (and other
11 items) with the minimum of blood loss.

12
13 Figs. 24-35 show a sequence of steps involved in
14 utilising the introducer and haemostatic valve of the
15 invention to emplace the endovascular prosthesis of the
16 invention in the aorta to span across a sub-renal
17 aneurysm, with the prosthesis having the advantage of
18 supra-renal anchorage but without interfering with
19 renal blood flow.

20
21 While certain modifications and variations have been
22 described above, the invention is not restricted
23 thereto, and other modifications and variations can be
24 adopted without departing from the scope of the
25 invention.

26
27 Figure 24 shows a basic introducer assembly 11 which
28 may be used to introduce a stent 12 (see Fig. 25A).
29 The assembly 11 includes the capsule 130 for deploying
30 the anchor stent 100A. Stent 12 and sleeve 13 (see
31 Fig. 25B) may be assembled and structured together to
32 form an endovascular prosthesis 14 according to the
33 invention (see Fig. 25C). In use, the stent 12 and
34 sleeve 13 are compacted in a collapsed form and fitted
35 within a cartridge 15 (shown in outline for clarity in
36 Fig. 26) which are fitted to an introducer assembly 11.

1 The capsule 130 is shown containing the anchor stent
2 100A. A complete introducer assembly 16 is shown in
3 Fig 27 and includes a bayonet attachment 23A.

4
5 Figure 28 illustrates the introducer sleeve 17 and a
6 dilator tip 22. A guide wire 134 is fed through the
7 dilator tip 22 as sleeve 17 is inserted into the
8 patient. A haemostatic valve 19 of the type previously
9 described herein is attached to the dilator 23 of which
10 only handle 20 is visible in the diagram. The
11 haemostatic valve 19 may be opened and closed by use of
12 a rotatable handle 21.

13
14 Figure 29 illustrates the dilator 23 once it has been
15 withdrawn from the introducer sleeve 17. In order to
16 facilitate withdrawal of the dilator 23 from the
17 introducer sleeve 17 the haemostatic valve 19 is opened
18 by rotating the rotatable handle 21 in the direction of
19 the arrow. The dilator 23 is unlocked via the bayonet
20 attachment shown as 23A. The dilator 23 is completely
21 withdrawn from the sleeve 17 and the guideline 134,
22 ~~leaving the guide wire 134 and the sleeve 17 within the~~
23 body of the patient.

24
25 The complete introducer assembly 16 can then be passed
26 along the introducer sleeve 17 by attaching the guide
27 wire 134 to the nosecone 130 of the introducer assembly
28 16 and utilising the bayonet attachment 23A to lock the
29 introducer assembly 16 and haemostatic valve 19
30 together (see Fig. 30). The haemostatic valve 19 will
31 be opened just sufficiently to allow the passage of the
32 nose cone 130 and the rest of the endovascular
33 prosthesis into the patient's body whereupon the
34 haemostatic valve is closed (see Fig. 31). The
35 prosthesis is then deployed by pushing the introducer
36 assembly in at point A, as indicated, (see Fig. 32).

1 Once the nosecone 130 appears at point C (this being
2 monitored continuously) handle 15 is used to pull the
3 whole apparatus backwards (along arrow B) such that the
4 introducer sleeve 17 is pulled down the prosthesis (as
5 opposed to the prosthesis being pushed out of the sleeve
6 17). Fig. 32 shows the partial deployment of the
7 prosthesis and in Fig. 33 the prosthesis is almost
8 fully deployed. The complete deployment of the
9 prosthesis is achieved when the sleeved section of the
10 stent is clear of the introducer sleeve 17. After
11 checking correct positioning of the main stent, the
12 nosecone 130 is pushed forward to release the supra-
13 renal anchor 100A as previously described (see Fig.
14 34).

15
16 The rear of the nosecone 130 is tapered (see Figs. 34
17 and 9C) for easy withdrawal. Removal of the introducer
18 assembly 16 can be achieved by withdrawing the nosecone
19 130 through the fully deployed prosthesis and
20 withdrawing the introducer sleeve 17 from haemostatic
21 valve 19. The guide wire 134 and introducer sleeve 17
22 are all removed as one assembly (see Fig. 35).

23
24 Various mesh patterns suitable for a stent according to
25 the invention are shown in Figs. 36-38. The mesh
26 illustrated in Fig. 36A comprises a diagonally offset
27 row 30 of diamond-like shapes 31, the diamonds being
28 connected together to form a horizontal row by a
29 linking elements 32 having two bends therein. Thus the
30 full length of linking elements 32 exceeds the direct
31 length between the points connected thereby. These
32 linking elements 32 give flexibility to the
33 longitudinal and circumferential expansion of the
34 stent. Rows 30 of the diamond-like shapes 31 are
35 connected in a longitudinal direction by diagonally
36 disposed struts 33. Fig. 36B is the unexpanded form of

1 the mesh of Fig. 36A and Fig. 36C is an enlarged view
2 of the circled portion of Fig 36B illustrating the
3 detail of the connections.
4

5 An alternative mesh suitable for a stent of the present
6 invention is shown in Figs. 37A, B and C. The mesh
7 illustrated in Fig. 37A may be viewed as a series of
8 zig-zag elements 40 arranged in a longitudinal manner
9 and connected above and below to its neighbouring zig-
10 zag element 40 by diagonally disposed struts 41. Each
11 zig-zag element 40 is characterised by alternate struts
12 42 of the zig-zag having an additional "S"-shaped bend
13 43 therein. Struts 42 therefore have a greater length
14 than the direct distance between their ends.
15 Alternating with struts 42 to form the zig-zag element
16 40 are straight struts 44. The mesh illustrated in
17 Fig. 37B is a plan view of an unexpanded mesh. Fig.
18 37C is an enlarged view of a section of Fig. 37B
19 wherein typically the wire thickness is 0.149 mm.
20

21 Fig. 38A illustrates an alternative mesh suitable for a
22 stent of the present invention mesh. In this
23 embodiment, a row 50 of connected diamond-like sections
24 51 are arranged longitudinally and connected to
25 adjacent rows of diamond-like sections via linking
26 elements 52 on alternate diamonds. The linking
27 elements 52 are approximately "S"-shaped. In the
28 embodiment illustrated linking elements 52 are aligned
29 longitudinally, but it may be advantageous for these to
30 be off set in neighbouring rows. In the mesh
31 illustrated the connecting points 53 in alternate
32 neighbouring diamonds have been omitted. This imparts
33 greater flexibility to the mesh. Fig. 38B is a view of
34 the unexpanded mesh of Fig. 38A wherein the
35 approximately "S"-shaped linking elements 52 are
36 clearly visible between each of the rows 50 of diamond-

1 like sections 51.

2

3 In each of Figures 36-38 the "S"-shaped linking element
4 or "S"-shape vertices of the individual sections impart
5 increased flexibility to the stents, whilst maintaining the
6 structural integrity thereof.

7

8

1 CLAIMS

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1. An endovascular prosthesis for a vascular aneurysm, the prosthesis comprising a tubular

membrane means which is substantially impermeable to blood and which is disposable to convey blood between substantially non-aneurysmal regions on either side of the aneurysm, the prosthesis further comprising selectively deployable anchor means for anchoring in the vascular wall at an anchoring location displaced from the aneurysm, the anchor means being linked to the tubular membrane means by link means comprised in the prosthesis, the link means being such as to cause minimal turbulence in side-branching blood vessels branching from a point between the aneurysm and the anchoring location

2. An endovascular prosthesis as claimed in Claim 1 where in said anchor means comprises an expandable metal mesh annular stent.

3. An endovascular prosthesis as claimed in Claim 2 wherein said anchor means is unclad by any membrane or fabric.

4. An endovascular prosthesis as claimed in any one of Claims 1 to 3 wherein the link means comprises at least one longitudinally extending strut or wire.

5. An endovascular prosthesis as claimed in any one of Claims 1 to 4 wherein the tubular membrane means comprises a sleeve of fabric located over an expandable metal mesh tubular stent which is in a radially collapsed form for emplacement of the

1 prosthesis and which is expandable when located to
2 shunt the aneurysm.

3

4 6. An endovascular prosthesis as claimed in any one
5 of Claims 1 to 5 wherein the anchor means stent
6 and the tubular membrane means stent are each
7 formed from shape memory material.

8

9 7. An endovascular prosthesis as claimed in Claim 6
10 wherein the anchor means stent and the tubular
11 membrane means stent are each formed from nitinol.

12

13 8. A stent formed from a mesh characterised in that
14 said mesh comprises a linking element wherein each
15 end of said element is connected at a connecting
16 point to the mesh and wherein the length of said
17 element exceeds the distance between the
18 connecting points.

19

20 9. A stent as claimed in Claim 8 wherein said linking
21 element comprises an "S"-shaped bend.

22

23 10. A stent as claimed in Claim 9 wherein said linking
24 element is substantially "S"-shaped.

25

26 11. A mesh stent wherein the mesh is formed from rows
27 of diamond-like elements arranged longitudinally
28 and linked together by connecting elements, at
29 least one of which is a linking element as defined
30 in any one of Claims 8 to 10.

31

32 12. A mesh stent having a zig-zag element formed from
33 linking elements as defined in any one of Claims 8
34 to 10 alternating with straight sections.

35

36 13. A stent as claimed in any one of Claims 8 to 12

1 formed from shape memory material.

2

3 14. An endovascular prosthesis as claimed in any one
4 of Claims 1 to 7 comprising a stent as claimed in
5 any one of Claims 8 to 13.

6

7 15. An introducer for endovascular emplacement of an
8 endovascular prosthesis according to any one of
9 Claims 1 to 7 or 14, the introducer comprising a
10 flexible tubular guide means externally
11 dimensioned for passage along a vascular duct from
12 an extracorporeal location to the site of the
13 aneurysm and to the anchoring location, the guide
14 means being internally dimensioned to encompass
15 the prosthesis in its initially radially collapsed
16 state without preventing controlled longitudinal
17 displacement of the prosthesis relative to the
18 guide means during emplacement of the prosthesis,
19 the introducer further comprising a hollow capsule
20 for containing the anchor means in an initially
21 radially collapsed state, one end of the capsule
22 being detached from the remainder of the capsule
23 and inserted inside the remainder of the capsule
24 to lie within or adjacent the other end of the
25 capsule such as to leave the remainder of the
26 capsule between said inserted one end and the
27 other end of the capsule for containing the
28 collapsed anchor means, the introducer
29 additionally comprising displacement control means
30 for longitudinally displacing the capsule with
31 respect to the tubular guide means, the introducer
32 further comprising capsule end replacement means
33 for replacing said one end of the capsule
34 following deployment of the anchor means whereby
35 to facilitate withdrawal of the capsule following
36 emplacement of the prosthesis.

1 16. An introducer as claimed in Claim 15 wherein the
2 capsule end replacement means comprises spring
3 means disposed within the capsule between the
4 opposite ends thereof to urge the detached end of
5 the capsule towards its replaced position.
6

7 17. An introducer as claimed in Claim 15 wherein the
8 capsule end replacement means comprises a Bowden
9 cable means having a core wire threaded through
10 the longitudinal axis of the introducer as a guide
11 wire for the introducer, and having a Bowden
12 sheath coupled to the detached end of the capsule.
13

14 18. A surgical package comprising the operative
15 combination of an endovascular prosthesis as
16 claimed in any one of Claims 1 to 7 or 14 and an
17 introducer as claimed in any one of Claims 8 to
18 10, the tubular membrane means of the prosthesis
19 being in an initially radially collapsed
20 configuration and located within the tubular guide
21 means, the anchor means of the prosthesis being in
22 an initially radially collapsed configuration and
23 located with the capsule, the anchor means being
24 linked to the tubular membrane means by the link
25 means such that the anchor-encompassing capsule is
26 also linked to the tubular membrane means, the
27 capsule being disposed at the leading end of the
28 tubular guide means, the displacement control
29 means being threaded through the tubular guide
30 means and through the tubular membrane means.
31

32 19. A surgical package as claimed in Claim 18 wherein
33 the displacement control means extends through the
34 end of the tubular guide means remote from the end
35 of the guide means initially holding the
36 prosthesis for extracorporeal control of the

1 displacement of the capsule.

2

3 20. A haemostatic valve comprising an elastomeric
4 sleeve, a first end of the sleeve being sealed to
5 a first sealing means, a second end of the sleeve
6 being sealed to a second sealing means, and pinch
7 control means for controllably pinching the sleeve
8 where it extends between the two sealing means
9 whereby controllably to seal around the tubular
10 guide means or the displacement control means as
11 it passes through the sleeve.

12

13 21. A haemostatic valve as claimed in Claim 20
14 comprising coupling means to allow connection and
15 disconnection to the introducer.

16

17 22. A haemostatic valve as claimed in either one of
18 Claims 20 and 21 wherein the pinch control means
19 comprises rotation control means for controllably
20 inducing relative rotation of the first and second
21 sealing means about a common axis.

22

23 23. A haemostatic valve as claimed in Claim 22 wherein
24 the rotation control means comprises bearing means
25 rotationally coupling the two sealing means for
26 relative rotation about a common axis, spring
27 means acting between the two sealing means to bias
28 them into relative rotation in a sense tending to
29 induce rotational collapse of the sleeve, and
30 manually engageable means attached to or forming
31 part of the sealing means by which the bias of the
32 spring means may be controllably counteracted by
33 the application of manual force such as
34 controllably to open the valve by a selected
35 amount.

36

- 1 24. Use of a haemostatic valve as claimed in any one
2 of Claims 20 to 23 in combination with the
3 surgical package of Claim 19.
4
5 25. A surgical package as claimed in Claim 19 further
6 comprising a haemostatic valve means as claimed in
7 any one of Claims 20 to 23.

8

9

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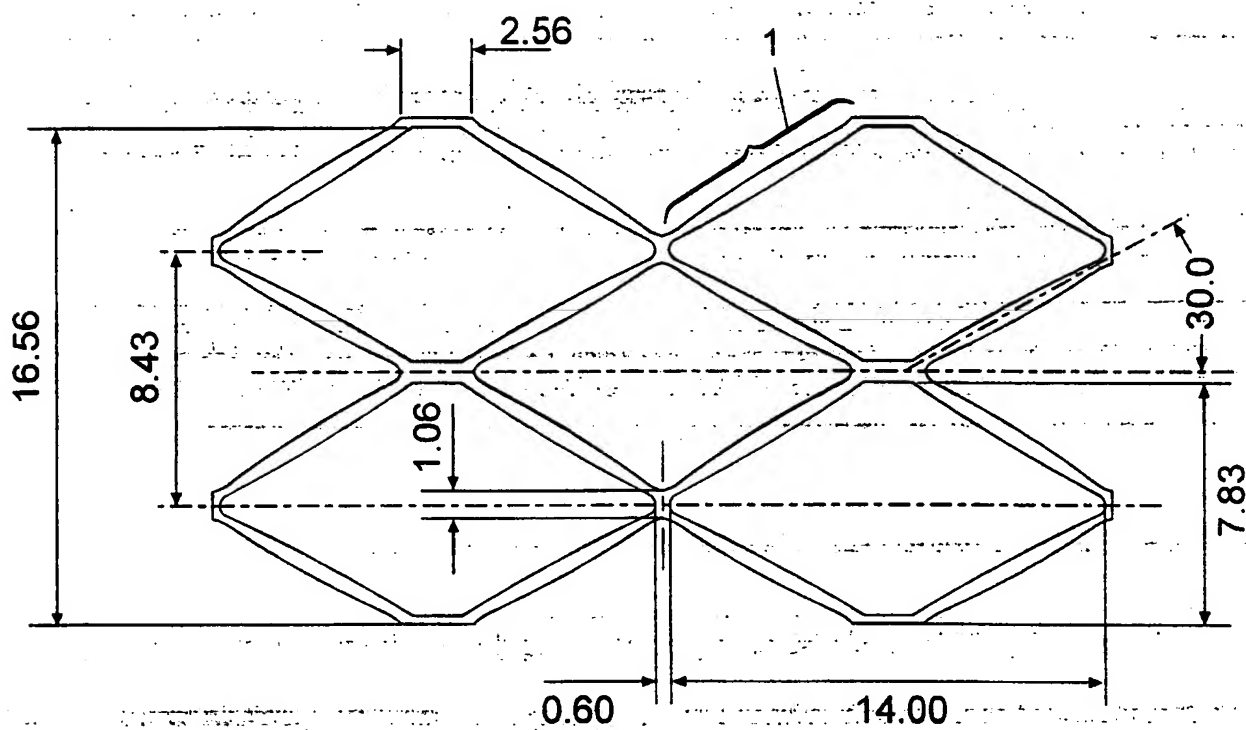


Fig. 1

2 / 29

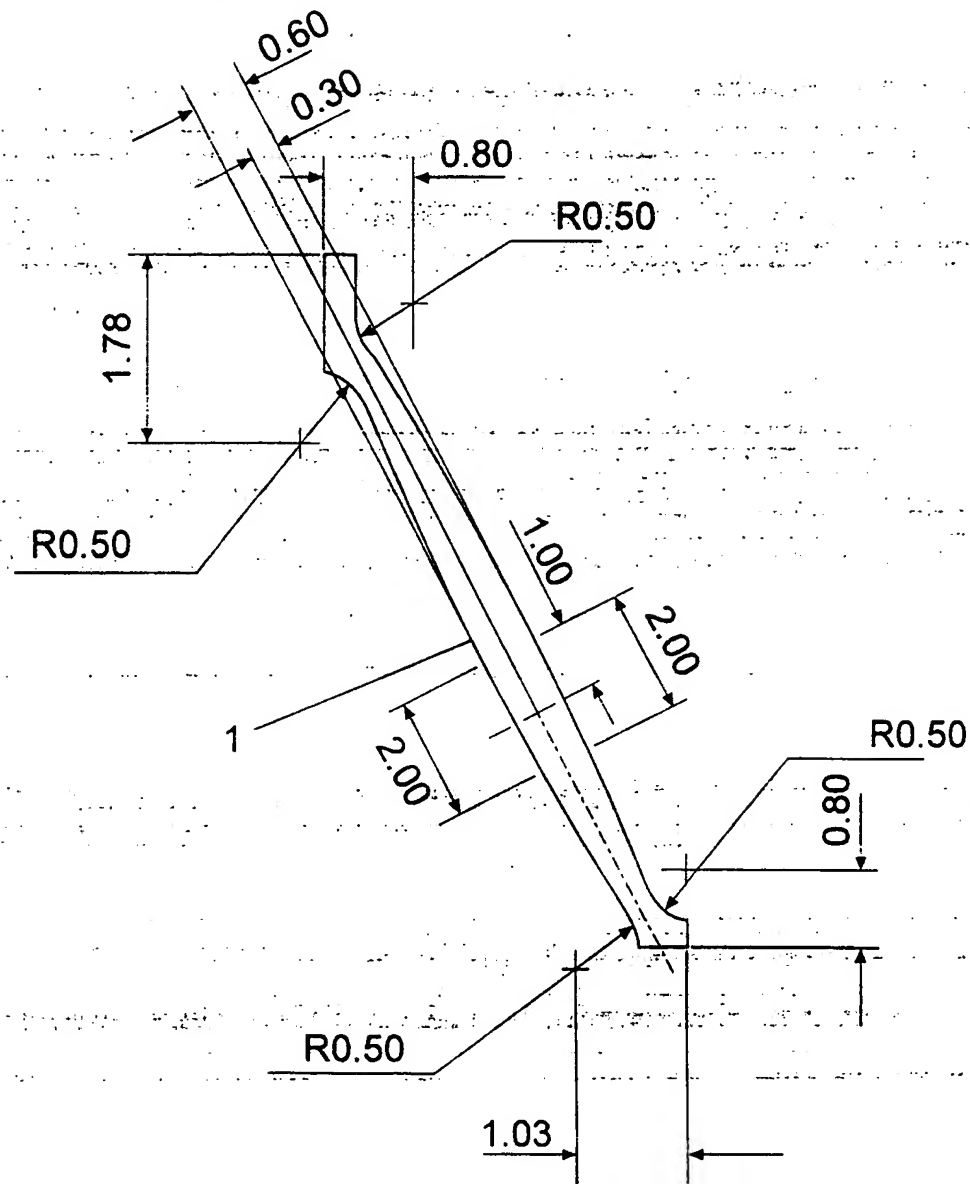


Fig. 2

3 / 29

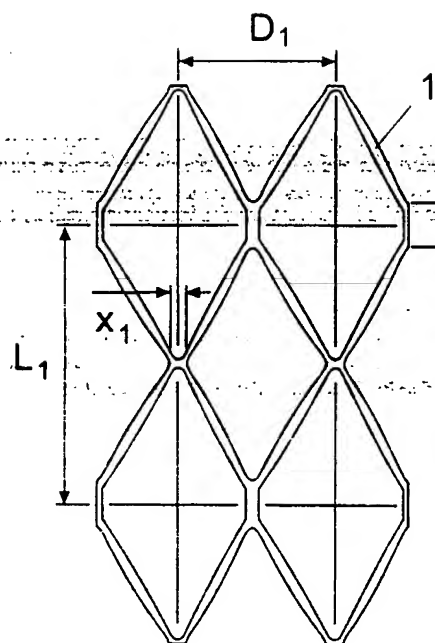


Fig. 3

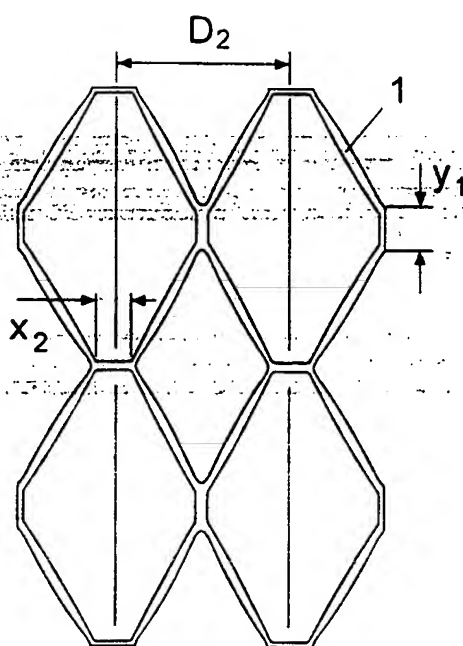


Fig. 4

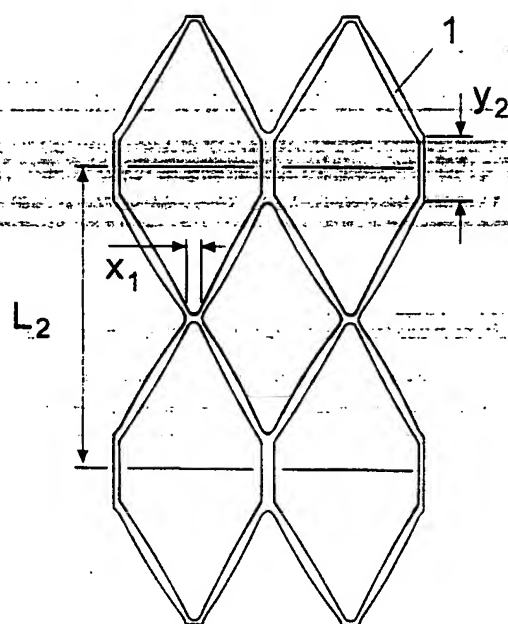


Fig. 5

4 / 29

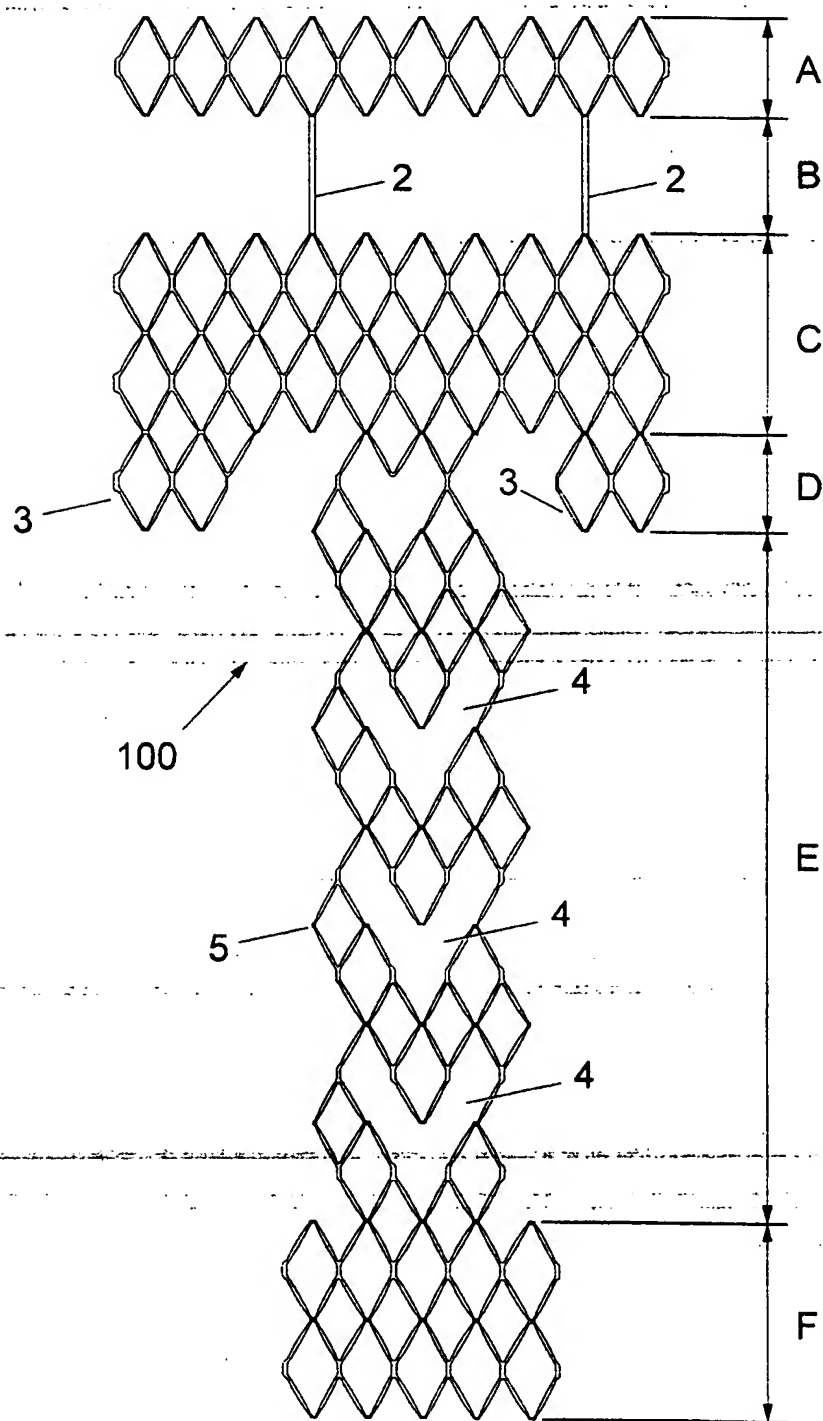


Fig. 6
SUBSTITUTE SHEET (RULE 26)

5 / 29

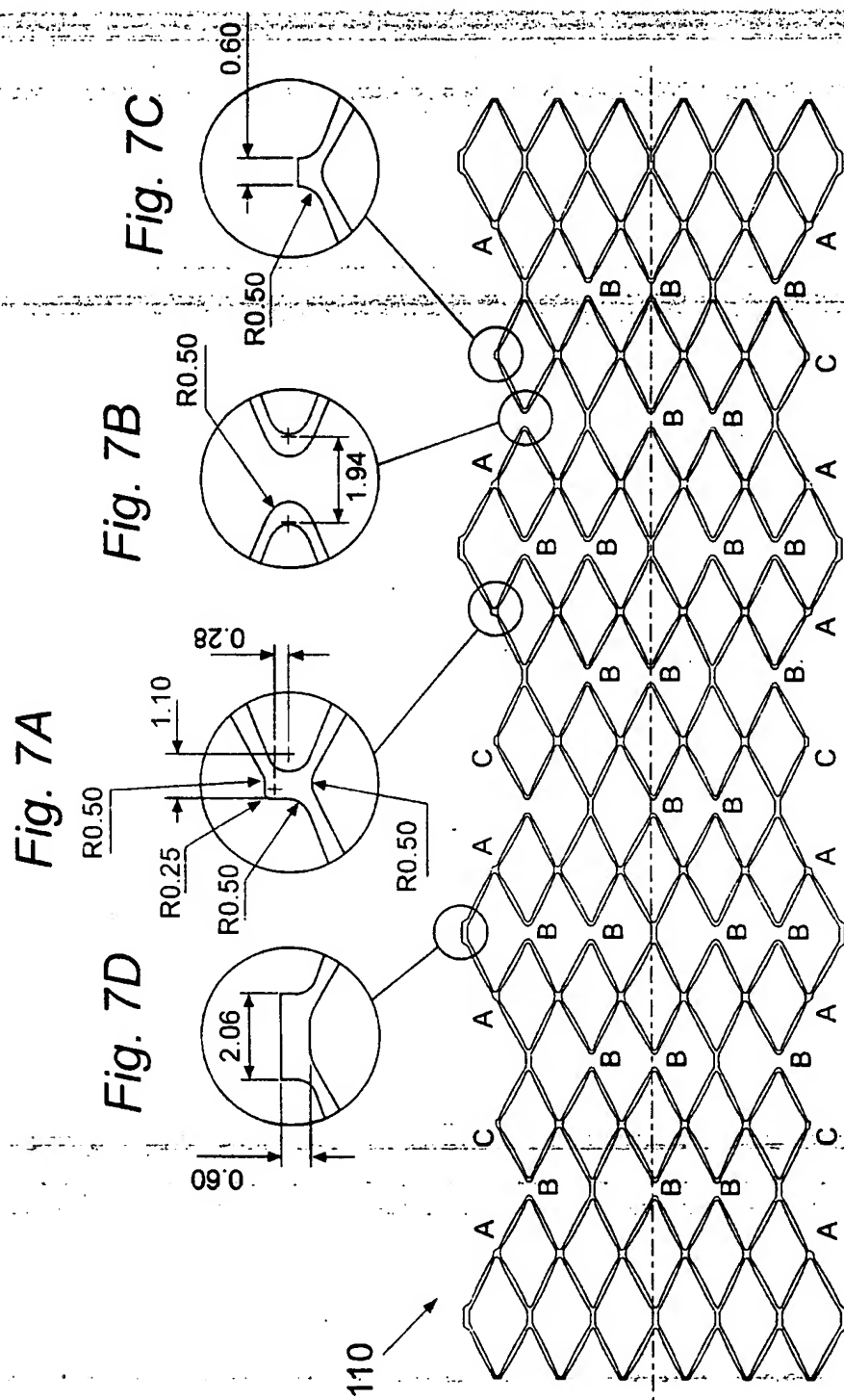
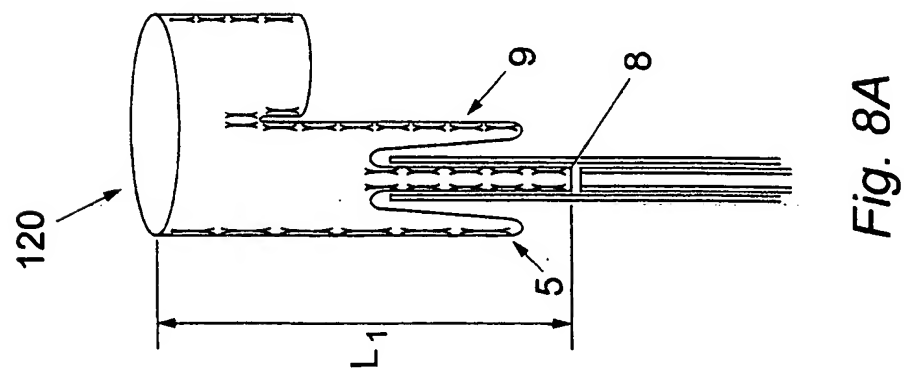
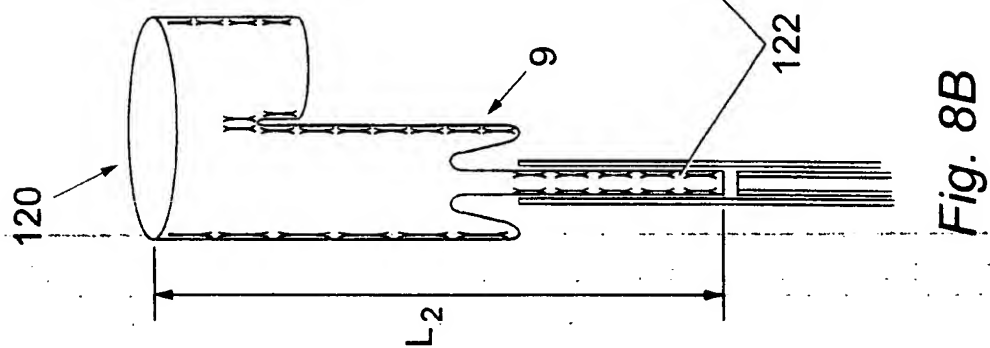
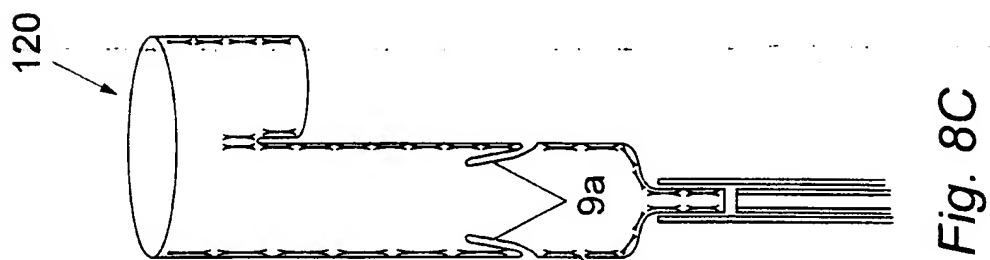
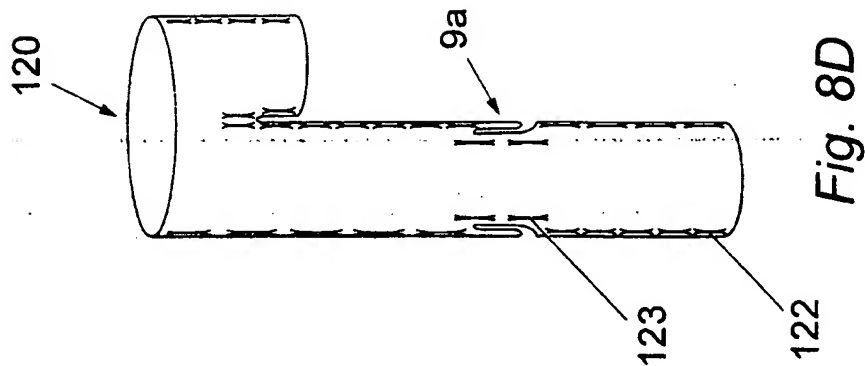


Fig. 7

6 / 29



7 / 29

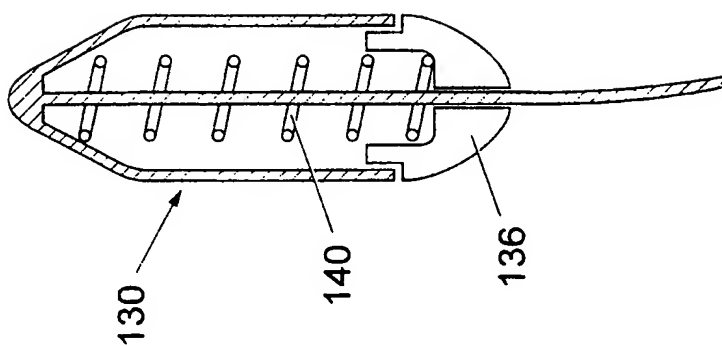


Fig. 9C

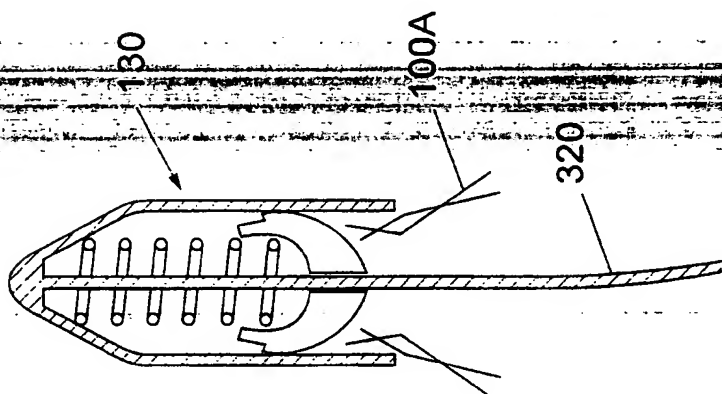


Fig. 9B

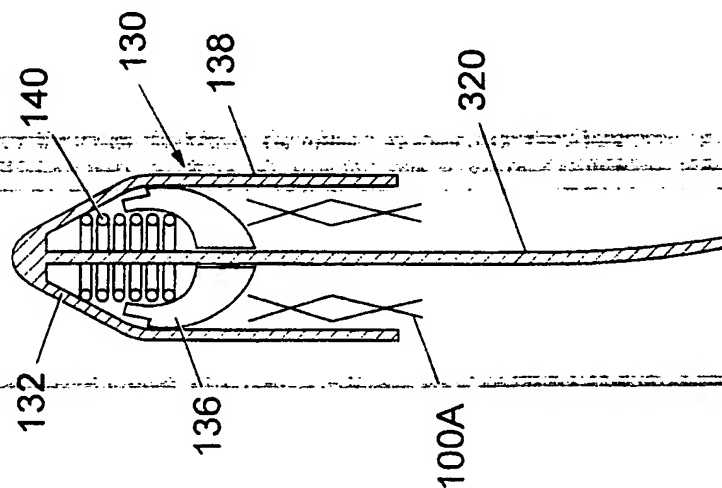


Fig. 9A

8/29

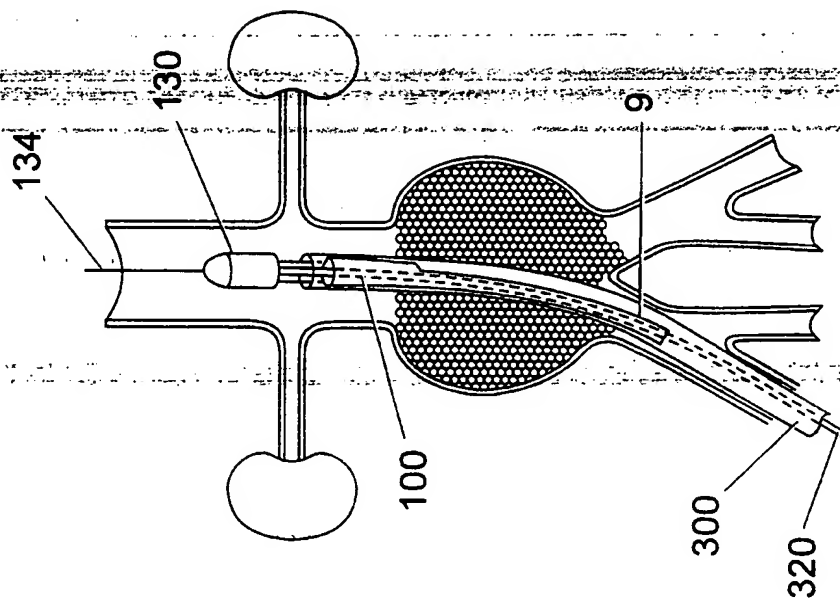


Fig. 11

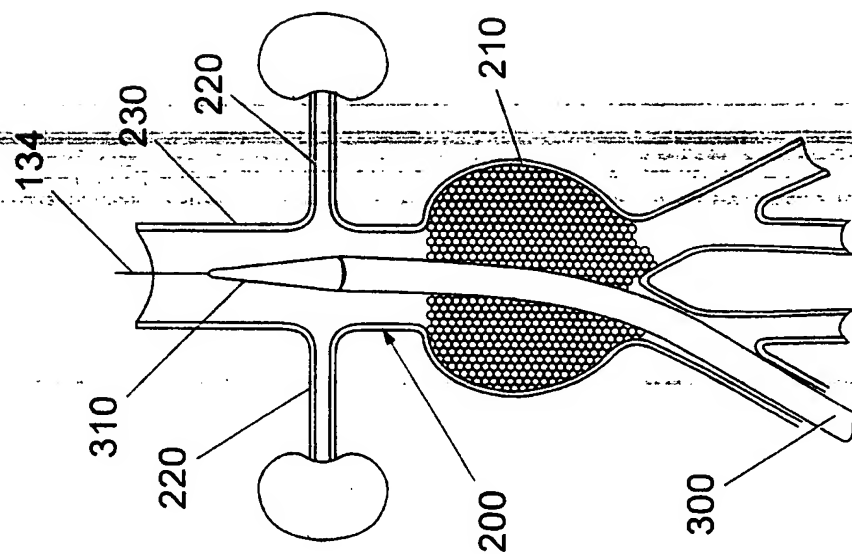


Fig. 10

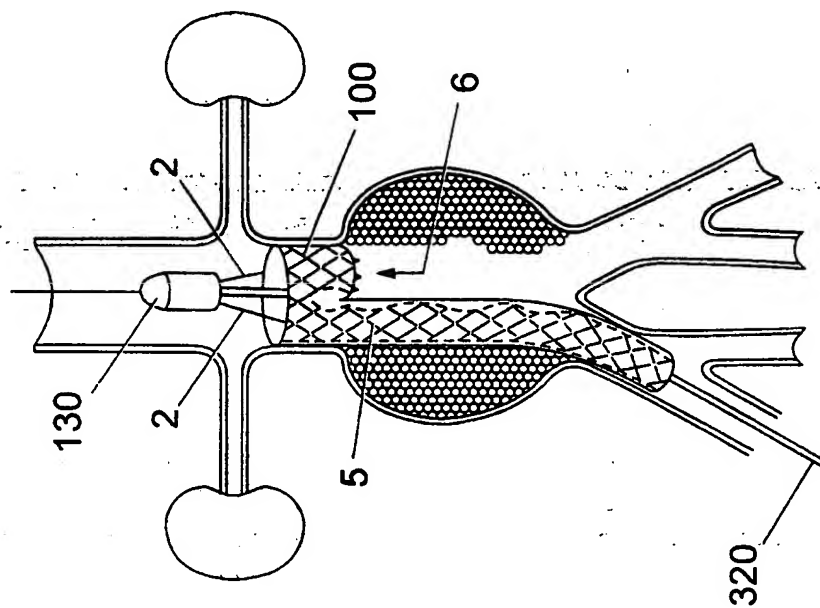


Fig. 13

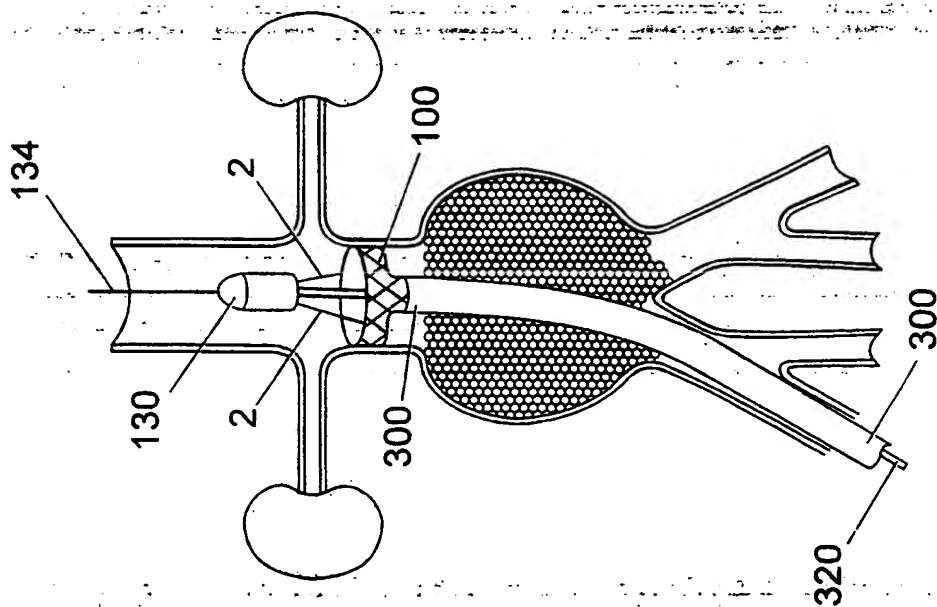


Fig. 12

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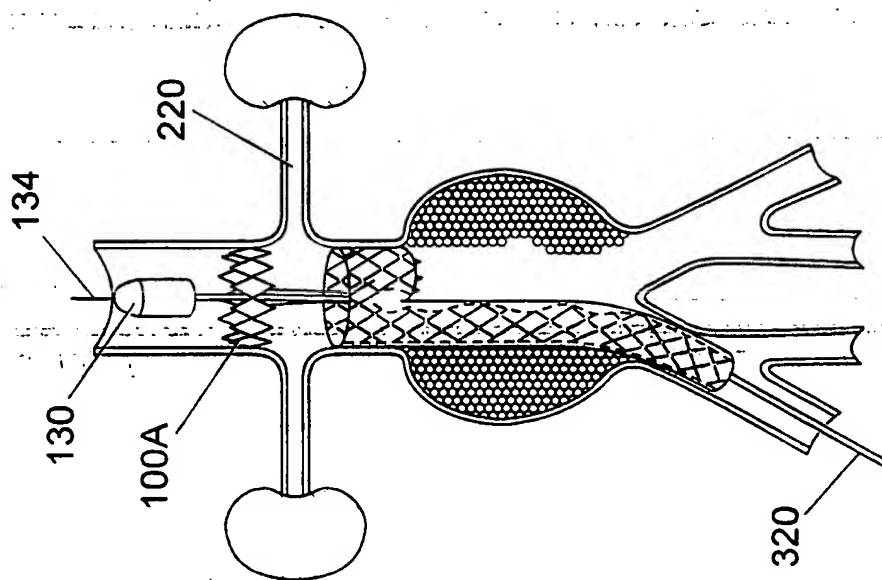


Fig. 15

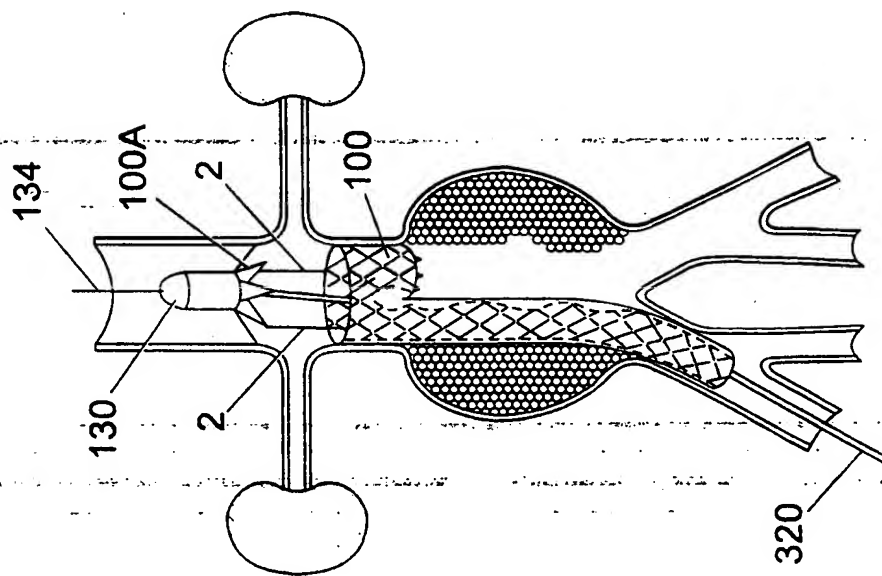


Fig. 14

11 / 29

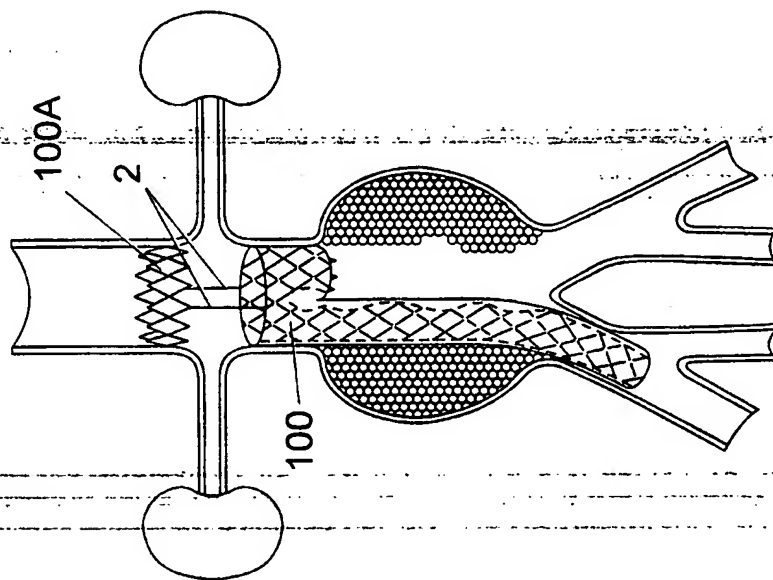


Fig. 17

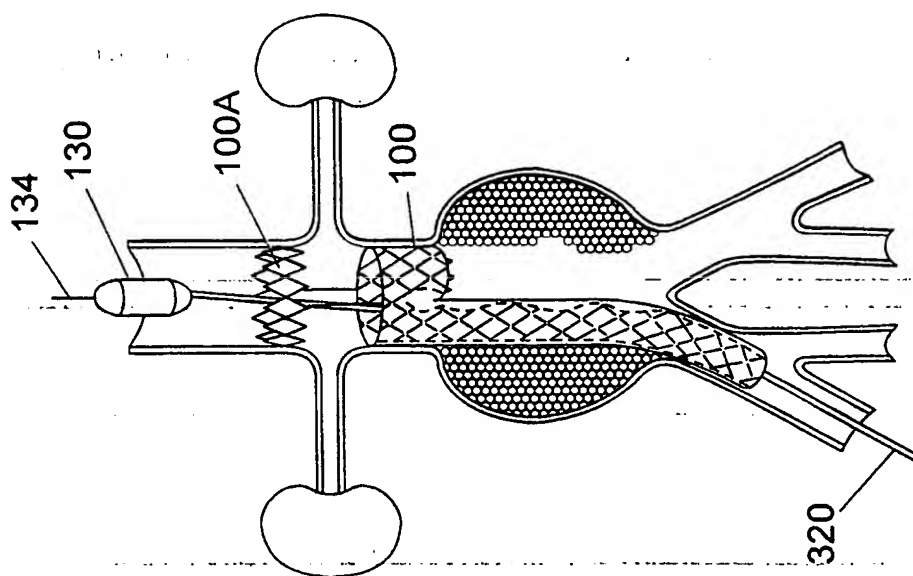


Fig. 16

12 / 29

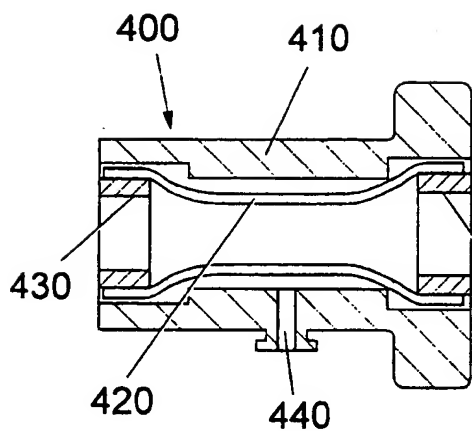


Fig. 18A

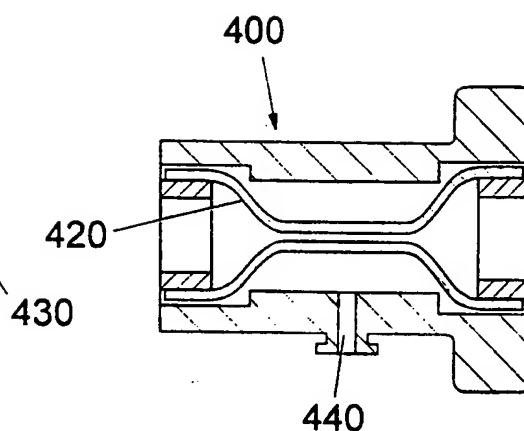


Fig. 18B

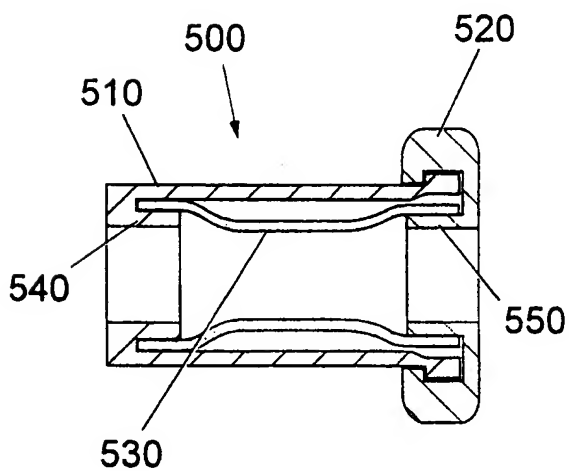


Fig. 19A

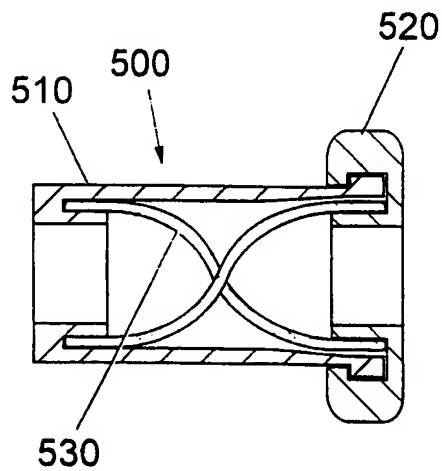


Fig. 19B

13 / 29

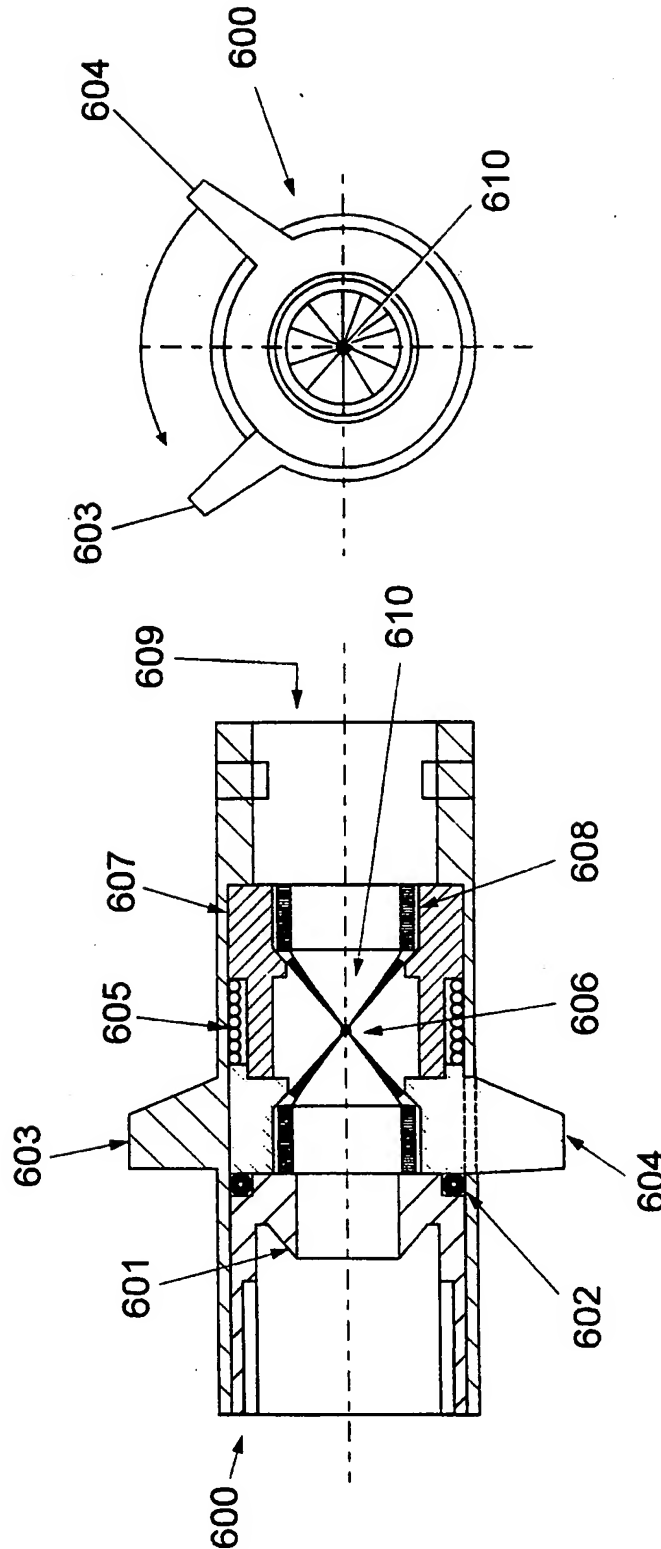
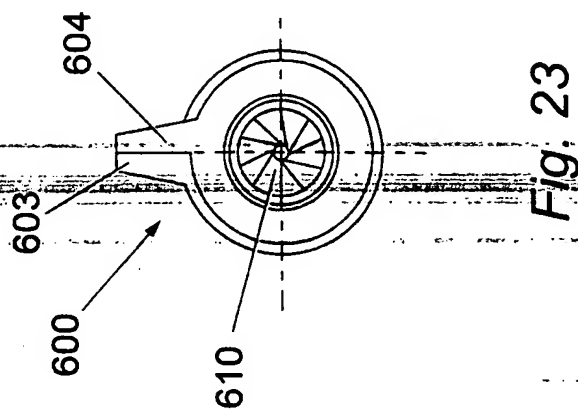
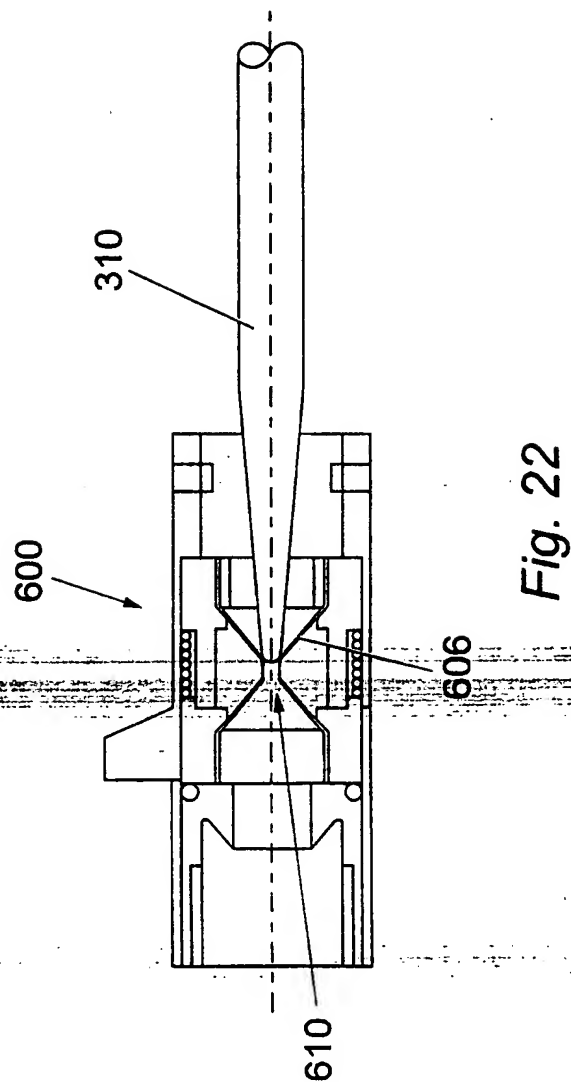


Fig. 21

Fig. 20

14 / 29



15 / 29

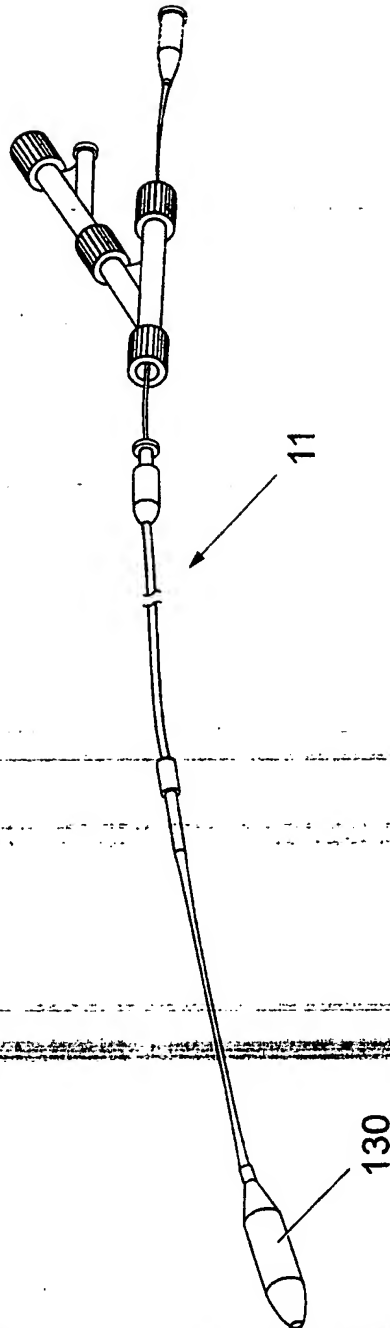


Fig. 24

16 / 29

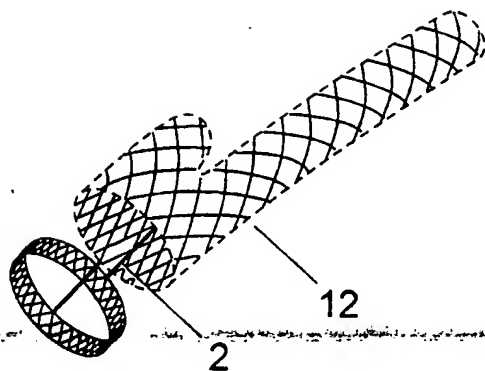


Fig. 25A

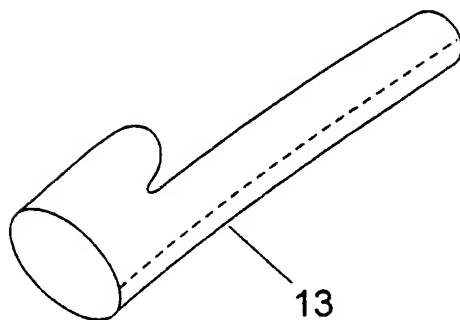


Fig. 25B

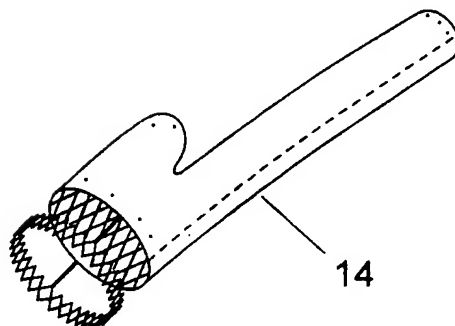


Fig. 25C

17 / 29

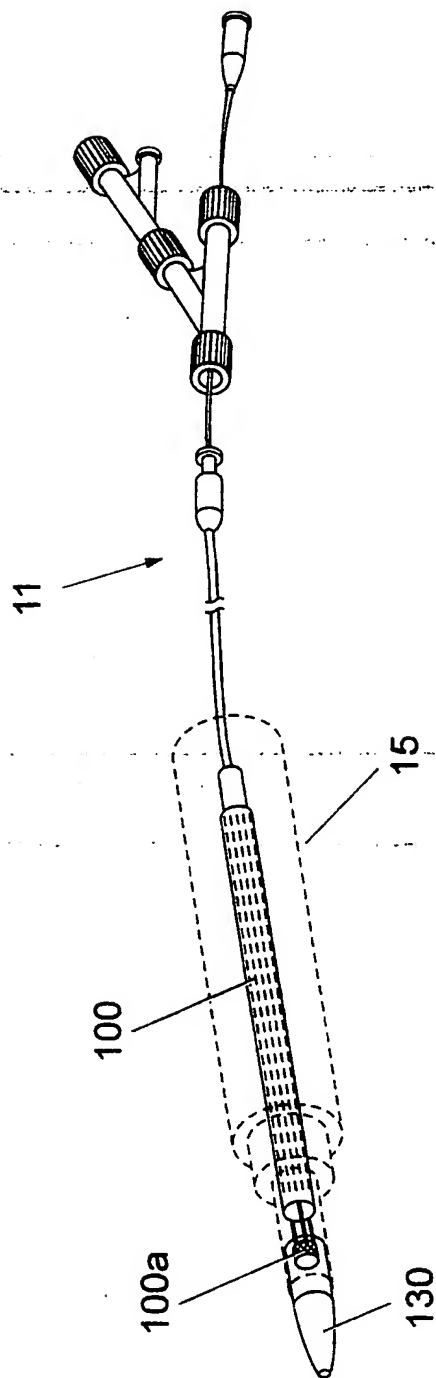


Fig. 26

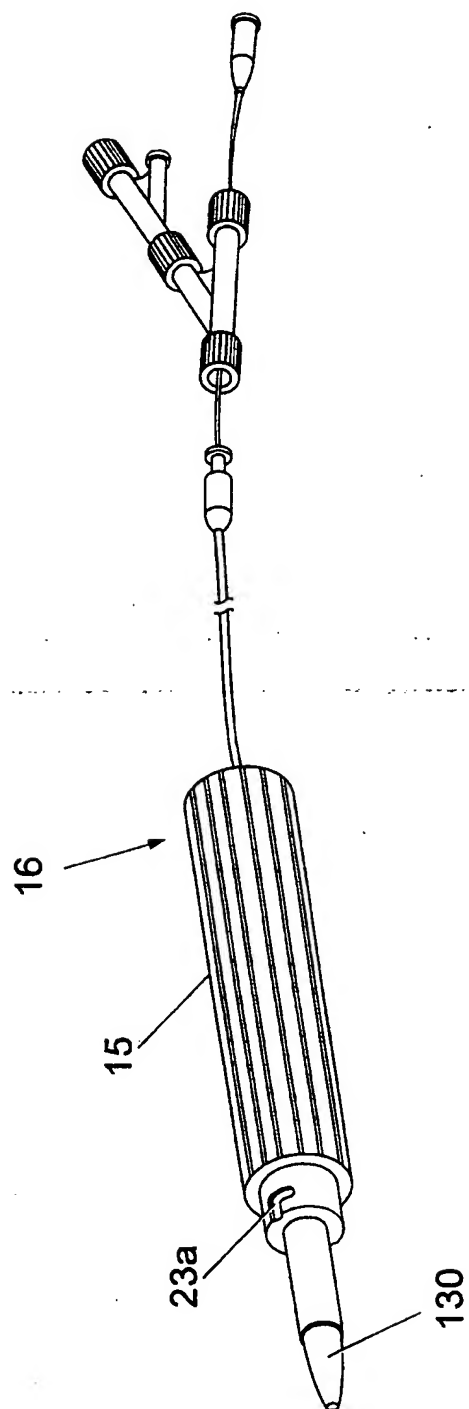


Fig. 27

19 / 29

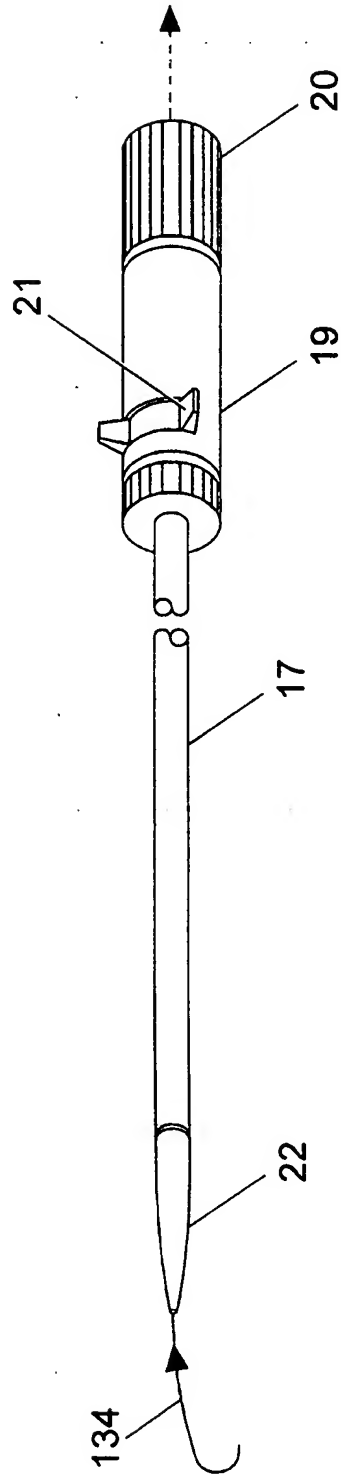


Fig. 28

20 / 29

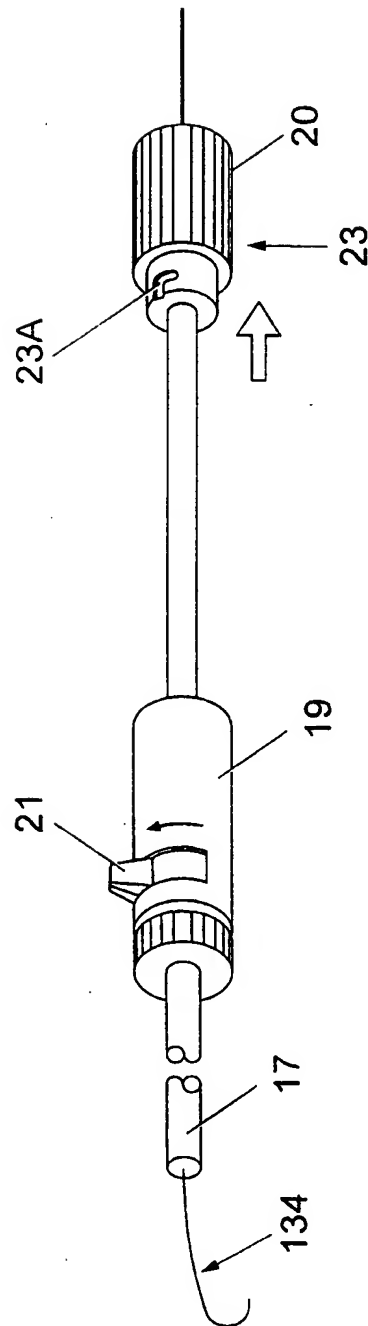


Fig. 29

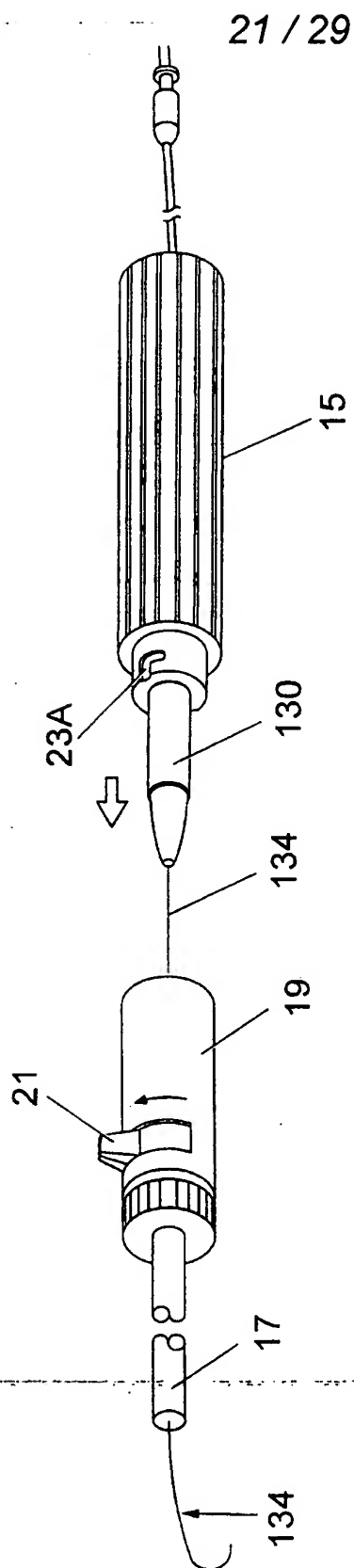


Fig. 30

22 / 29

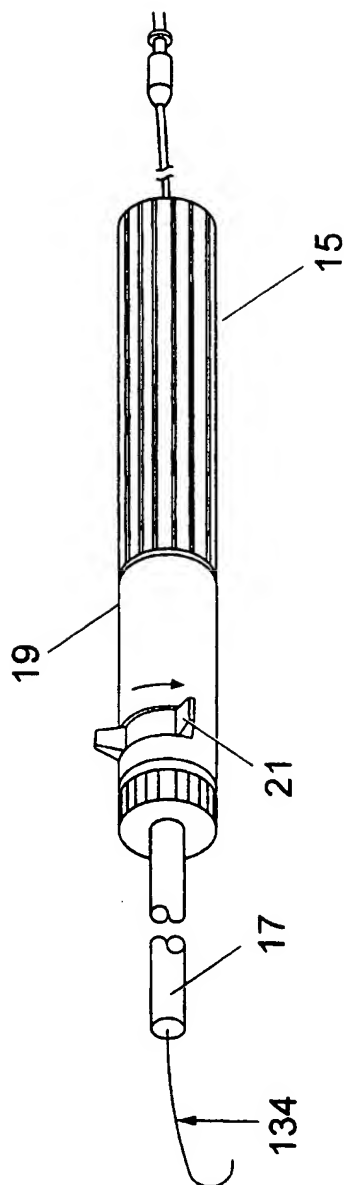
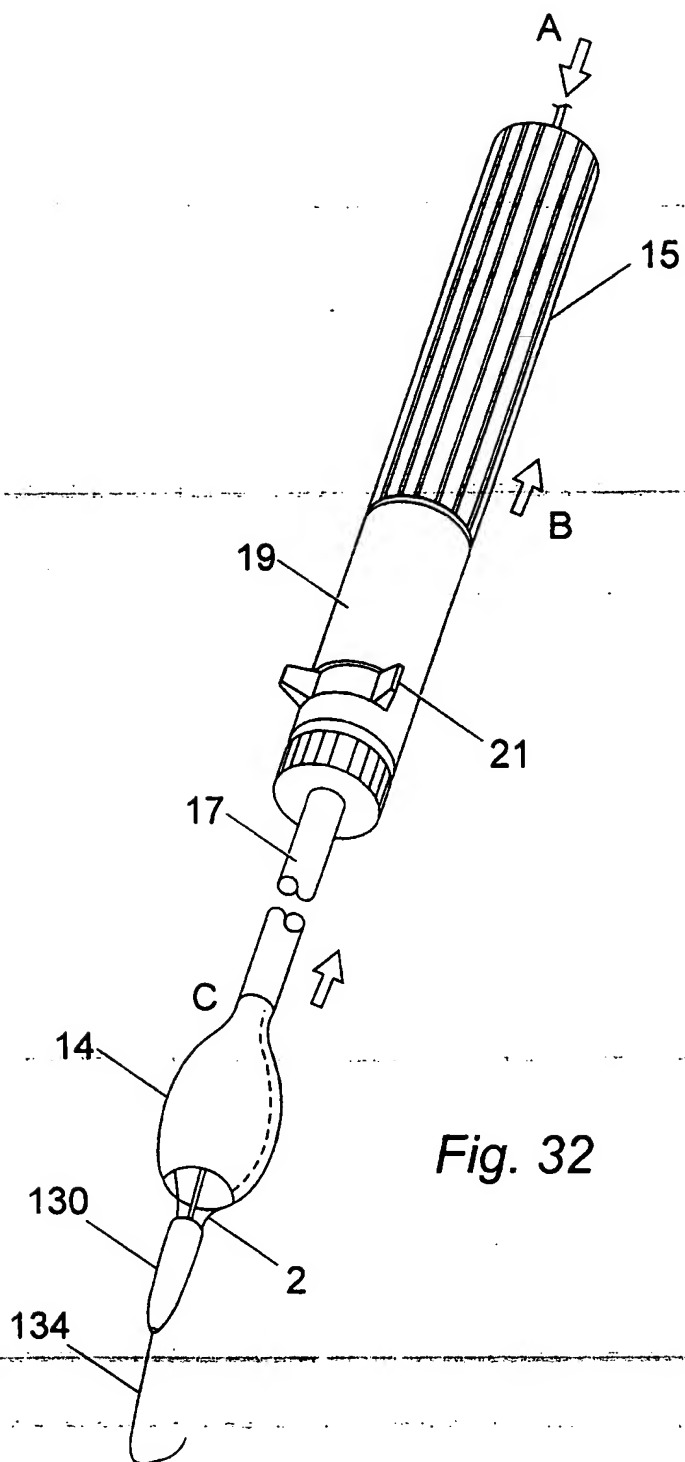


Fig. 31

23 / 29



24 / 29

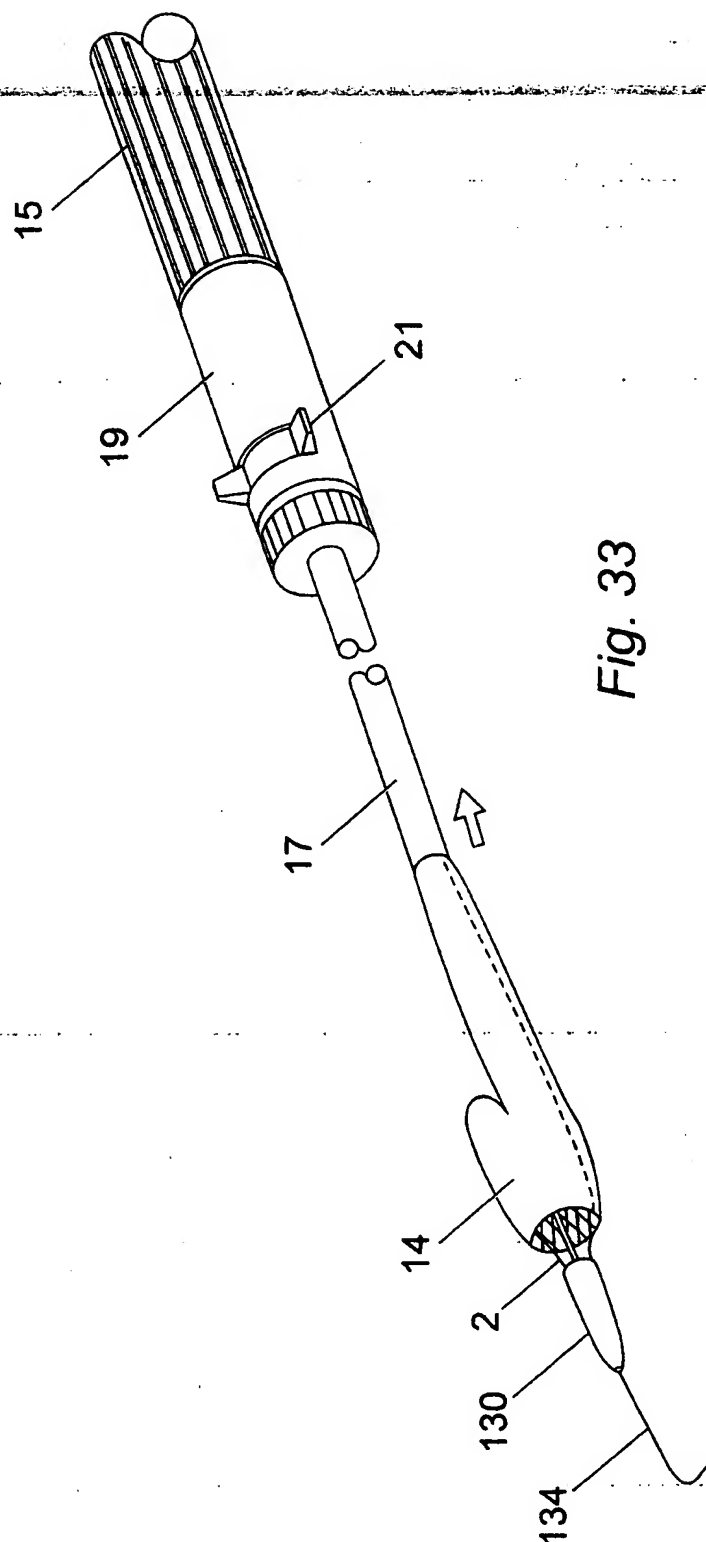


Fig. 33

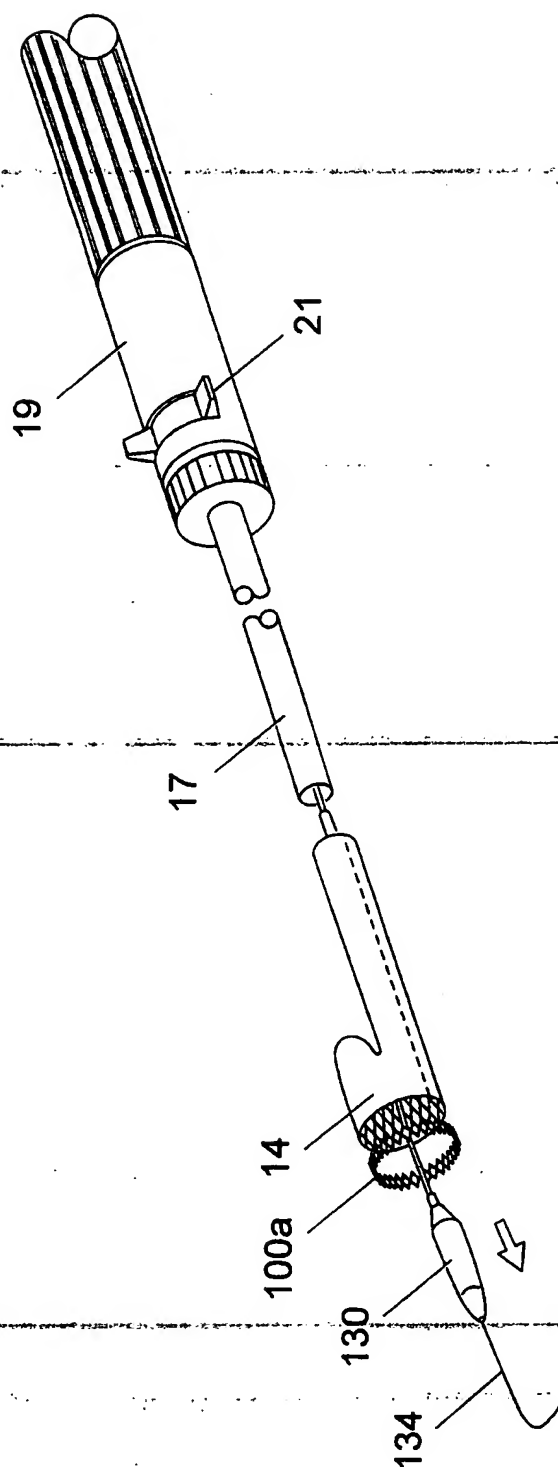


Fig. 34

26 / 29

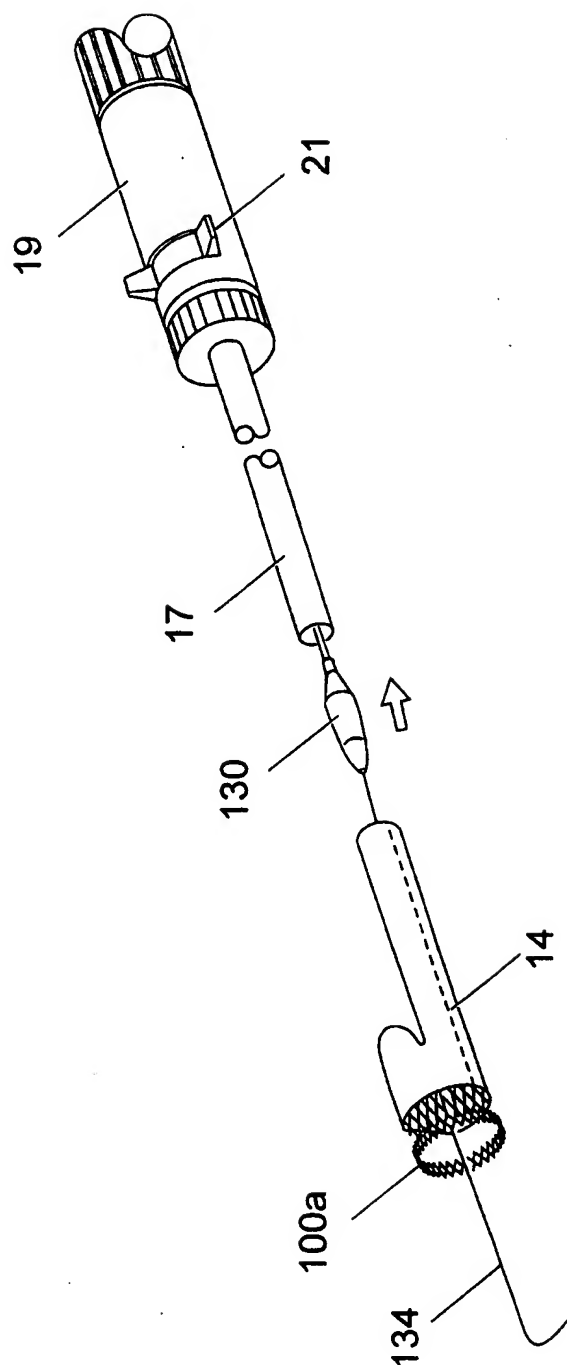
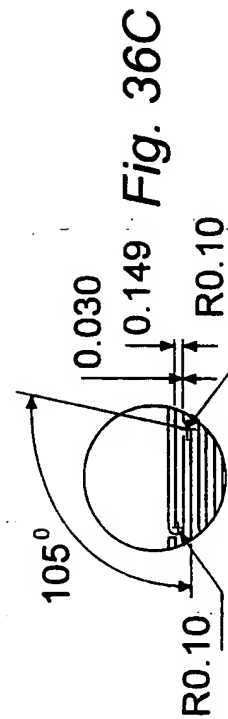
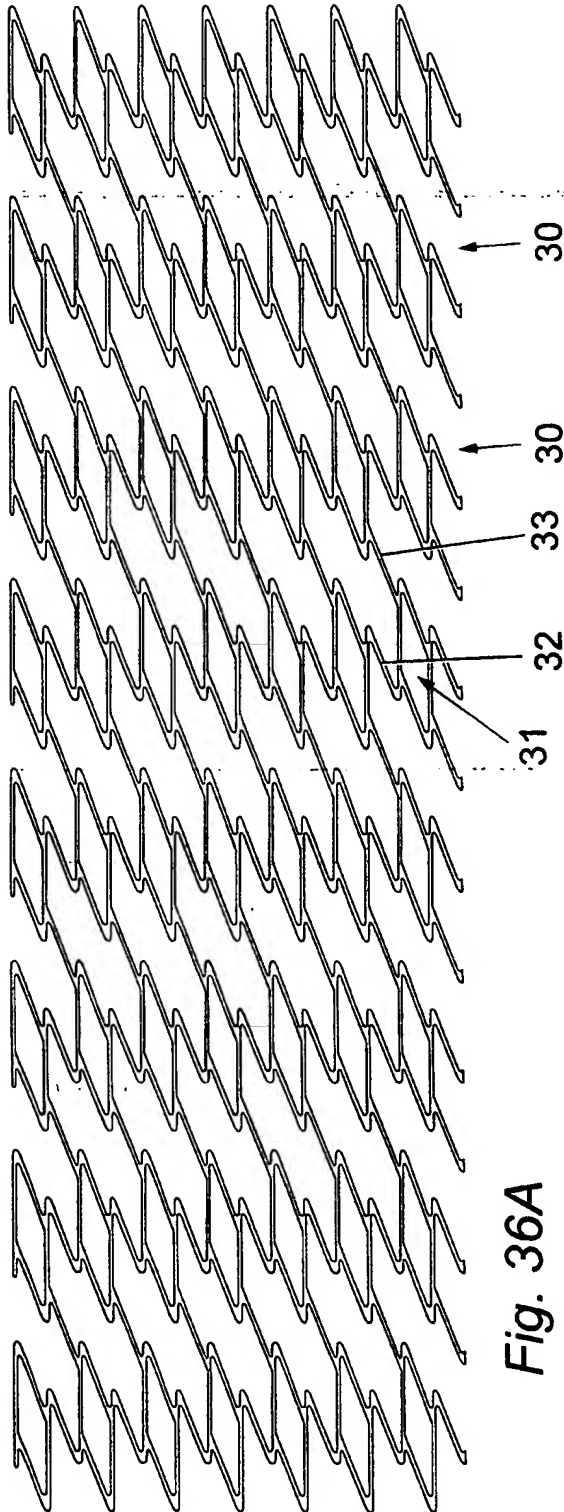
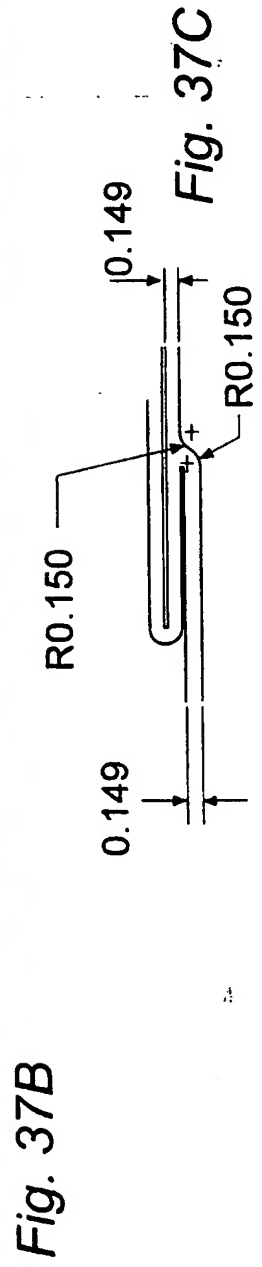
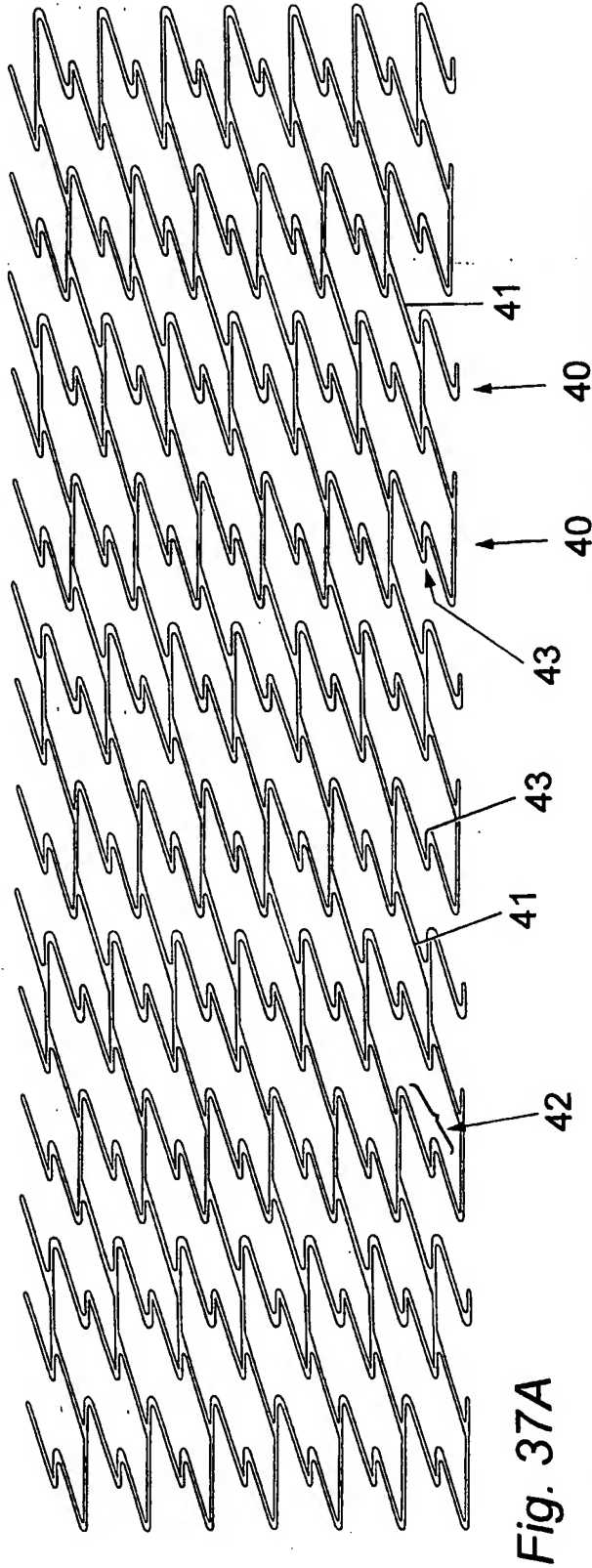


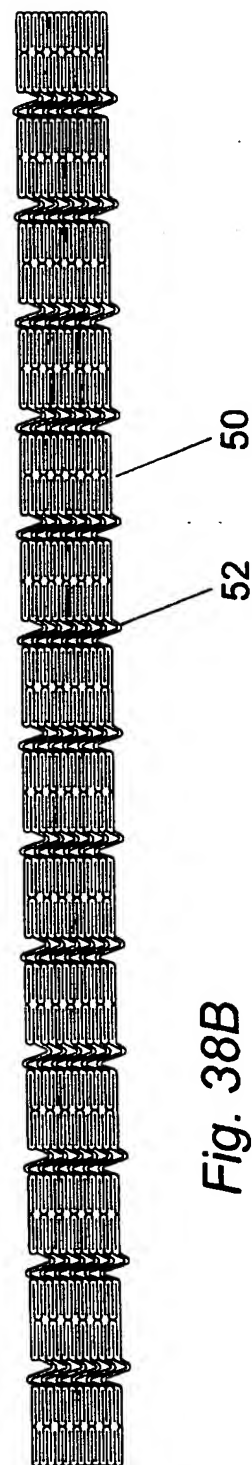
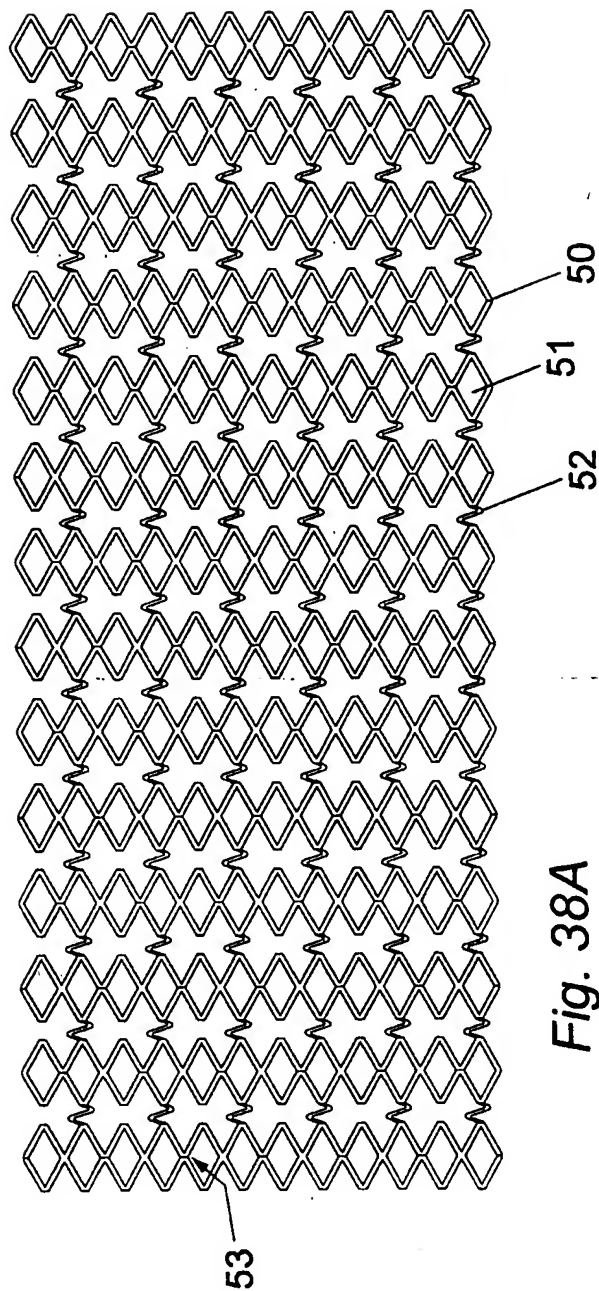
Fig. 35



28 / 29



29 / 29



INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/00867

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	see column 10, line 11 - line 14; claims; figure 7	2-5, 8, 14, 15, 18, 20, 24
A	US 5 464 449 A (RYAN TIMOTHY J ET AL) 7 November 1995 see column 5, line 46 - line 55; figure 14	1, 15, 20
P, A	FR 2 743 293 A (DENIS JEAN MARC) 11 July 1997 see page 5, line 6 - line 11; claim 4; figure 4	1, 13

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 July 1998

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl,
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INTERNATIONAL SEARCH REPORT

Inte. onal Application No

PCT/GB 98/00867

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